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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUSSEX COUNTY, NEW JERSEY,

Plaintiff,

v.

PURDUE PHARMA L.P., DR. RICHARD SACKLER, ESTATE OF MORTIMER SACKLER, ESTATE OF RAYMOND SACKLER, ABBOTT LABORATORIES, CEPHALON, INC., TEVA PHARMACEUTICAL INDUSTRIES INC., ENDO INTERNATIONAL PLC, JANSSEN PHARMACEUTICALS, INC., INSYS THERAPEUTICS, INC., MALLINCKRODT PLC, ABC CORPORATIONS 1-100 ENGAGED IN THE MANUFACTURING OF OPIOIDS, AMERISOURCEBERGEN, MCKESSON, CARDINAL HEALTH, ABC CORPORATIONS 1-100 ENGAGED IN THE DISTRIBUTION OF OPIOIDS, CVS HEALTH CORPORATION, WALGREENS BOOTS ALLIANCE, INC., COSTCO WHOLESALE CORPORATION, RITE AID CORPORATION, AND ABC CORPORATIONS 1-100,

Defendants.

Case No.

JURY TRIAL DEMANDED

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1. Plaintiff Sussex County ("County" or "Plaintiff") brings this action against Defendants: Purdue Pharma L.P.; Dr. Richard Sackler; Estate of Mortimer Sackler; Estate of Raymond Sackler; Abbott Laboratories; Cephalon, Inc.; Teva Pharmaceutical Indusitrices Inc.; Endo International PLC; Janssen Pharmaceuticals, Inc.; Insys Therapeutics, Inc.; Malinkrodt PLC; ABC Corporations 1-100 engaged in the manufacturing of opioids; AmerisourceBergen; McKesson; Cardinal Health; ABC Corporations 1-100 engaged in the distribution of opioids; CVS Health Corporation; Walgreens Boots Alliance, Inc.; Costco Wholesale Corporation; Rite Aid Corporation; and ABC Corporations 1-100, to prevent future harm and to redress past wrongs.

I. INTRODUCTION

2. America is in the midst of an ever-expanding epidemic of addiction to opioids – both in the form of prescription pain killers and heroin.

3. In the next hour, five Americans will fatally overdose from opioids[1]; two opioid dependent babies will be born[2]; and a significant number of prescription opioid addicts will turn to heroin.[3] During that same time, opioid manufacturers will earn approximately $2.7 million from opioids.[4]

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[1] Center for Disease Control and Prevention, Drug Overdose Death Data, https://www.cdc.gov/drugoverdose/data/statedeaths.html (last visited February 20, 2018).

[2] Jean Y. Ko, PhD, *et al.*, Public Health Burden of Neonatal Abstinence Syndrome (March 10, 2017), https://www.cdc.gov/mmwr/volumes/66/wr/mm6609a2.htm (last visited February 20, 2018).

[3] Patrick Keefe, *The Family that Built an Empire of Pain*, New Yorker (Oct. 23, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain (hereinafter "Keefe, *Empire of Pain*").

[4] Dina Gusovsky, "American Consume Vast Majority of World's Opioids, CNBC (April 27, 2016), https://www.cnbc.com/2016/04/27/americans-consume-almost-all-of-the-global-opioid-supply.html.

4. Prescription opioids include brand-name drugs and generics like oxycodone and hydrocodone, and are derived from opium and possess properties similar to heroin. As such, prescription opioids are highly addictive and present precarious risks to patients and the community.

5. The cause of the epidemic, and of the harms for which this lawsuit seeks redress, is not the opioids themselves, but Defendants' conduct. As detailed below, Defendants engaged in a concerted, avaricious campaign to flood this country with opioids by deliberately manipulating (and failing to police) every layer of the distribution and prescription process in order to push pills out the door in volumes and through channels they knew would create conditions ripe for addiction and abuse. Communities, such as Sussex County, were predictably inundated by Defendants' man-made flood---and seek relief for all the predictable, damning consequence that have followed.

6. The opioid addiction epidemic was ignited in the 1990s by Purdue Pharma, at the instance and direction of Richard, Mortimer, and Raymond Sackler.

7. Historically, because it was accepted within the medical community that opioids were extremely addictive and debilitating for treatment of chronic pain, opioids were used only to treat short-term acute pain or for palliative (end-of-life) care.

8. Purdue Pharma, manufacturer and marketer of OxyContin, changed this perception, not with scientific advances but through a deceptive marketing scheme aimed at convincing doctors (and the public at large) that opioids can be prescribed for long-periods of time with little to no risk of addiction—a blatantly false premise.

9. Purdue's fraudulent and deceptive marketing scheme worked, and sales for OxyContin skyrocketed, resulting in ***billions*** of dollars for Purdue and its top executives—including, Richard, Mortimer, and Raymond Sackler.

10. As detailed below, Purdue's fraudulent and deceptive marketing scheme was joined and/or adopted by each of the Defendants, as well as those who acted in concert with them.

11. The record profits achieved by Purdue Pharma and others were earned at the expense of millions of Americans who predictably fell to the tsunami of opioids that Purdue and others unleashed, and the communities which were left to address the consequence of the crisis created by Defendants.

12. Since the plan's inception, deaths from opioids have been rising sharply.

13. Today, drug overdoses kill more Americans under age 50 than anything else.

14. More than 42,000 opioid-related deaths occurred in 2016.[5] Experts predict that opioids could kill 500,000 Americans over the next decade, and that the annual death toll will increase by at least 35 percent between 2015 and 2027—that means more than 93,000 deaths a year by 2027.[6]

15. There are now more than 100 deaths a day from opioids, and the devastation blankets the United States—from bucolic New England suburbs to the farms in California, from beaches in the Florida Keys to the White Mountains of New Hampshire.[7]

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[5] Center for Disease Control and Prevention, Drug Overdose Death Data, https://www.cdc.gov/drugoverdose/data/statedeaths.html (last visited February 20, 2018)

[6] Max Blau, *STAT Forecast: Opioids could kill nearly 500,000 Americans in the next decade* (June 27, 2017), https://www.statnews.com/2017/06/27/opioid-deaths-forecast/ (last visited February 20, 2018)

[7] Center for Disease Control and Prevention, Drug Overdose Death Data, https://www.cdc.gov/drugoverdose/data/statedeaths.html (last visited February 20, 2018)

16. The epidemic touches all demographics: new born children and the elderly, men and women, veterans and civilians, farmers and musicians, lawyers and construction workers, stay-at-home moms and the homeless.[8]

17. All the while, the communities where the newly addicted live struggle to contain the epidemic and ameliorate its consequences.

18. Addiction is on the rise as well. It is estimated that approximately 2.6 million Americans over the age of 12 were addicted to prescription opioids and heroin in 2015. That number continues to climb.[9]

19. In 2012, only 241,000 privately insured patients were diagnosed with opioid dependence.

20. By 2016, that number was 1.4 million. And that does not even account for the hundreds of thousands more battling addictions while on Medicaid or Medicare, or while uninsured.[10]

21. And, increasingly, those who have an opioid dependency, but cannot obtain a prescription (either because they cannot afford it, or cannot find a doctor to fill it), turn from prescription pills to heroin or fentanyl – which is less expensive, often more accessible, and can be even more potent and more dangerous.[11]

[8] https://www.statnews.com/2017/06/27/opioid-deaths-forecast/ (last visited February 20, 2018)

[9] https://www.statnews.com/2017/06/27/opioid-deaths-forecast/ (last visited February 20, 2018)

[10] *Id.*

[11] *Id.*

22. Indeed, 75 percent of patients in heroin treatment centers started their opioid use with prescription medications, not heroin.[12]

23. Based on these statistics, most Americans know someone that either is struggling with, has been impacted by, or has died from an opioid addiction.

24. In 1991, doctors wrote 76 million opioid prescriptions.[13] Less than a decade later (by 2000), that number had almost doubled, jumping to 131,000,000.[14] By the next decade (2012), the number had almost doubled again, to an alarming 259,000,000 prescriptions[15]--enough for every man, woman, and child to get at least one bottle of prescription opioid pills that year.

25. By 2015, the volume of opioids prescribed was enough for every American to be medicated around the clock for three weeks.

26. The increased sales of prescription opioids are not accompanied by an overall change in the amount of pain reported.[16]

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[12] Maia Szalavitz, "Five Myths About Heroin" (March 4, 2016), https://www.washingtonpost.com/opinions/five-myths-about-heroin/2016/03/04/c5609b0e-d500-11e5-b195-2e29a4e13425_story.html?utm_term=.40eeb3df6d96 (last visited February 20, 2018).

[13] *Id.*

[14] Christopher M. Jones, "*Prescription Drug Abuse & Overdose in the United States*" https://secure.in.gov/attorneygeneral/files/Jones_Indiana_RX_Meeting_-_CJONES(5).pdf (last visited February 20, 2018).

[15] *Opioid Painkiller Prescribing*, Centers for Disease Control and Prevention: Vital Signs (July 2014), https://www.cdc.gov/vitalsigns/opioid-prescribing/

[16] *Overdoses of Prescription Opioid Pain Relievers United States, 1999—2008,* Centers for Disease Control and Prevention: Vital Signs (November 4, 2011), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm; see also, Chang H, Daubresse M, Kruszewski S, et al. *Prevalence and treatment of pain in emergency departments in the United States, 2000 – 2010*. Amer. J. of Emergency Med. 2014; 32(5): 421-31.

27. This meteoric rise in prescriptions (and the attendant rise in addiction to and abuse of prescription opioids and heroin) is also not due to a medical breakthrough.

28. Rather, is has been Defendants' quest for greater profits by way of a fraudulent and deceptive marketing scheme—all at the expense of American lives and their communities—that has caused increases in prescriptions and addictions.

29. The cost of the opioid epidemic is estimated to have exceeded $1 trillion from 2001 to 2017, and is projected to cost an additional $500 billion by 2020.[17]

30. Accordingly, in addition to injunctive relief and damages for past costs incurred, Sussex County seeks monetary damages for the costs needed to prospectively abate, contain and minimize the impact of the epidemic on the County and its residents, including funding for: (i) treatment programs, including expanded educational programs, medication assisted treatment, and social services; (ii) programs to reduce demand, strengthen education in the community, and provide associated family support and child services; (iii) harm reduction programs, including improved access and training regarding naloxone and other overdose antidotes; and (iv) increased police and task force activity to reduce diversion of prescription opioids and the supply of illicit opioids, such as heroin and fentanyl.

II. PARTIES

A. Plaintiff

31. Plaintiff Sussex County, New Jersey ("County" or "Plaintiff") is located in New Jersey.

[17] *Economic Toll of Opioid Crisis In U.S. Exceeded $1 Trillion Since 2001*, https://altarum.org/about/news-and-events/economic-toll-of-opioid-crisis-in-u-s-exceeded-1-trillion-since-2001 (last visited February 20, 2018)

32. The County has incurred significant costs and a loss of resources attempting to curb the epidemic, impacting virtually every branch of the County—from emergency services, to the courts, to care facilities and clinics, to prisons, and to the police department.

33. The County has been compelled to spend increasing amounts of money and resources to combat the increasing opioid epidemic, including but not limited to:

(a) Medication costs for employees and retirees;

(b) Health insurance premiums paid on behalf of employees and retirees;

(c) Addiction treatment for employees and retirees;

(d) Costs related to absenteeism due to addiction in the workforce;

(e) Overdose- and addiction-related medical and hospital costs for employees and retirees;

(f) Overdose-related emergency room services for indigent members of the community and jail inmates;

(g) Detoxification, substance abuse treatment, and certain related medical care for jail inmates;

(h) Incarceration costs for opioid-related crimes;

(i) Police services associated with opioid arrests and overdose calls;

(j) Drug court and related judicial expenditures;

(k) Medical examiner and burial costs associated with overdoses and related medical conditions; and

(l) Homelessness services and mental health services related to opioid addiction.

34. The County has expended taxpayers' resources to address these harms caused by the opioid epidemic, as well as many others. In many cases, law enforcement has, due to the exigency and need, become the first responders to deal with the crisis. This is not only counter-productive to law enforcement's intended mission, but it is also not an effective way to stem of the epidemic of addiction.

35. Defendants can, and must, be held accountable.

B. Manufacturer Defendants

36. Defendant Purdue Pharma L.P. is a Delaware limited partnership formed in 1991 with headquarters located in Stamford, Connecticut and offices for Research and Development in Cranbury, New Jersey and Ewing, New Jersey, as well as facilities in Totowa, New Jersey that manufacture and distribute OxyContin. The company maintains four operational branches: Purdue Pharma L.P., the Purdue Frederick Company, Purdue Pharmaceutical Products L.P. and Purdue Products L.P. (referred to collectively herein as "Purdue").

37. Defendant Dr. Richard Sackler ("Dr. Sackler") is a board member and the former President and Co-Chairman of Purdue Pharma L.P. Dr. Sackler is the named inventor on multiple patents directed toward the opioids at issue in the opioid addiction epidemic.

38. Defendant the Estate of Mortimer Sackler ("Estate of M. Sackler") was co-CEO of Purdue Pharma during the crucial period of OxyContin's development and promotion.

39. Defendant the Estate of Raymond Sackler ("Estate of R. Sackler") was co-CEO of Purdue Pharma during the crucial period of OxyContin's development and promotion.

40. Defendant Abbott Laboratories ("Abbott") is an Illinois corporation with its principal place of business in Abbott Park, Illinois.

41. Defendant Cephalon, Inc. is a Delaware corporation with its headquarters and principal place of business located in Frazer, Pennsylvania.

42. Defendant Teva Pharmaceutical Industries Inc. ("Teva USA") is a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd. (Teva Ltd."), an Israeli corporation. Teva USA is a Delaware corporation with its principal place of business in Pennsylvania.

43. Teva USA and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva USA conducts Teva Ltd.'s sales and marketing activities for Cephalon in the United States and has done so since Teva Ltd.'s October 2011 acquisition of Cephalon. Teva USA holds out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Chicago, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. (Teva USA and Cephalon, Inc. collectively are referred to herein as "Cephalon.")

44. Defendant Endo International plc is an Irish public limited company with its headquarters in Dublin, Ireland. Endo Pharmaceuticals Inc. (together with Endo International plc, "Endo") is a Delaware corporation with its headquarters and principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is an indirectly wholly-owned subsidiary of Endo International plc.

45. Defendant Janssen Pharmaceuticals, Inc. ("Janssen") (formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica) is headquartered in Titusville, New Jersey and Raritan, New Jersey. Janssen is a wholly-owned subsidiary of Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

46. Defendant Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona.

47. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt Pharmaceuticals (together with Mallinckrodt plc, "Mallinckrodt") is a Delaware corporation with its headquarters in Hazelwood, Missouri.

48. ABC Corporations 1-100 engaged in the manufacturing of opioids.

C. Distributor Defendants

49. Defendant AmerisourceBergen is a Delaware corporation with its headquarters and principal place of business located in Chesterbrook, Pennsylvania.

50. Defendant McKesson is a Delaware corporation with its headquarters and principal place of business located in San Francisco, California.

51. Defendant Cardinal Health is a Delaware corporation with its headquarters and principal place of business located in Dublin, Ohio.

52. ABC Corporations 1-100 engaged in the distribution of opioids.

D. Pharmacy Defendants

53. Defendant CVS Health Corporation is a Delaware corporation with its headquarters and principal placed of business located in Woonsocket, Rhode Island.

54. Defendant Walgreens Boots Alliance, Inc. is a Delaware corporation with its headquarters in Deerfield, Illinois.

55. Defendant Costco Wholesale Corporation is a Washington corporation with its headquarters in Issaquah, Washington.

56. Defendant Rite Aid Corporation is a Delaware Corporation with its headquarters in Camp Hill, Pennsylvania.

57. ABC Corporations 1-100 engaged in the filling of prescriptions for opioids.

E. Defendants' Agents

58. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants or their officers, agents, employees, or other representatives while actively engaged in the management of Defendant's affairs within the course and scope of their duties and employment, and/or with Defendant's actual, apparent, and/or ostensible authority.

59. Jane and John Does 1-100, and ABC Corporations 1-100 actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendant's actual, apparent, and/or ostensible authority.

III. JURISDICTION AND VENUE

60. This Court has personal jurisdiction over Defendants because they transact and/or during the relevant period, have transacted business in the State of New Jersey and in Sussex County.

61. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 and 18 U.S.C. § 1961, *et seq*. as well as 28 U.S.C. § 1332.

62. Venue in this Court is proper under 28 U.S.C. § 1391(b).

IV. FACTUAL BACKGROUND

63. The opioid epidemic plaguing this country today has its roots not in the products themselves, but in Defendants' conduct, namely the development, marketing, manufacture, sale, and distribution of opioids from the 1990's to the present day.

64. As Senator McCaskill declared:

> The opioid epidemic is the direct result of a calculated marketing and sales strategy developed in the 90's, which delivered three simple messages to physicians. First, that chronic pain was severely undertreated in the United States. Second, that opioids were the best tool to address that pain. And third, that opioids could treat pain without risk of serious addiction. As it turns out, these messages were exaggerations at best and outright lies at worst.
>
> * * *
>
> Our national opioid epidemic is complex, but one explanation for this crisis is simple, pure greed.

A. Defendants' Quest for Profits, Not A Medical Breakthrough, Expanded the Market for Prescription Opioids to Long Term Use for "Every Day Pain"

65. By the late 1980s, the patent on its main source of revenue, a morphine pill for cancer patients called MS Contin, was running out for Purdue. Executives—including Richard, Raymond, and Mortimer Sackler—anticipated a massive loss of revenue as generic versions drove down the price of MS Contin.

66. In a 1990 memo, Robert F. Kaiko ("Kaiko"), vice president for clinical research, explained that "MS Contin may eventually face such serious generic competition that other controlled-release opioids must be considered."

67. Purdue already had developed a mechanism to extend a drug's release over time. In MS Contin, that mechanism made morphine last 8 to 12 hours. Purdue decided to use it on an old, cheap narcotic, oxycodone.

68. Sold under several names and formulations, including Percocet and Roxicodone, oxycodone controls pain for up to six hours.

69. With the delayed-release mechanism, executives, chief among them Richard Sackler, theorized that the drug would last 12 hours — at least twice as long as generics and the high end of MS Contin's range.

70. The first patients to use this drug, named OxyContin, were women recuperating from abdominal and gynecological surgery at two hospitals in Puerto Rico in 1989. In the clinical study, designed and overseen by Purdue scientists and paid for by the company, 90 women were given a single dose of the drug while other patients were given short-acting painkillers or placebos. None of the women were regular users of painkillers, so they were more susceptible to the effects of narcotics.

71. Even so, more than a third of the women given OxyContin started complaining about pain in the first eight hours and about half required more medication before the 12-hour mark, according to an FDA analysis of the study.

72. Despite the results of the clinical trials calling into question the 12-hour effectiveness, Purdue continued developing OxyContin as a 12-hour drug. It did not test OxyContin at more frequent intervals (i.e., intervals of less than 12-hours).

73. In statements to the patent office—contrary to the results of its clinical testing—Purdue claimed that OxyContin "provides pain relief [to] patient[s] for at least 12 hours after administration."

74. Purdue launched OxyContin in 1996, touting in advertisements in medical journals that it would last 12-hours. For example, in one advertisement, a spotlight illuminated two dosage cups, one marked 8 AM and the other 8 PM. "REMEMBER, EFFECTIVE RELIEF JUST TAKES

TWO," and another read "One dose relieves pain for 12 hours, more than twice as long as generic medications."18

75. Before OxyContin, doctors had viewed narcotic painkillers as dangerously addictive and primarily reserved their long-term use for cancer patients and the terminally ill. Purdue, led by the Sacklers, wanted a bigger market, and set out to create it through a campaign of false and deceptive marketing.

76. "We do not want to niche OxyContin just for cancer pain," a marketing executive explained to employees planning the drug's debut, according to minutes of the 1995 meeting.

77. Accordingly, under the direction of the Sacklers, Purdue spent $207 million on the launch of OxyContin, doubling its sales force to 600. Sales representatives were trained to pitch the drug to family doctors and general practitioners to treat common conditions such as back aches and knee pain.

78. With Percocet and other short-acting drugs, patients have to remember to take a pill up to six times a day, Purdue told doctors. OxyContin "spares patients from anxious 'clock-watching.'"

79. Purdue's marketing effort was brazen. Sales representatives showered prescribers with clocks and fishing hats embossed with "Q12h." The company invited doctors to dinner seminars and flew them to weekend junkets at resort hotels, where they were encouraged to prescribe OxyContin and promote it to colleagues back home.

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[18] Harriet Ryan, *et al.*, *"You Want A Description of Hell?" OxyContin's 12-Hour Problem*, L.A. Times (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/ (hereinafter "Ryan, *Description of Hell*").

80. Purdue sales representatives, who spent their days visiting doctors to talk up OxyContin, heard repeatedly that the drug did not last. In reports to Purdue headquarters, they wrote that many physicians were prescribing it for three or even four doses a day.

81. By 2000, data analyzed by company employees showed that one in five OxyContin prescriptions was for use every eight hours, or even more frequently.

82. But, managed care companies began denying these shorter prescriptions, and pharmacies refused to fill prescriptions for anything other than every twelve hours. This created a sales problem for Purdue and the Sacklers.

83. To solve this problem, the Purdue (incredibly without any scientific basis) sales team was instructed to recommend to physicians that they increase the strength of the dose of the prescriptions rather than the frequency and to remind physicians that there is no ceiling on the amount of OxyContin a patient can be prescribed.

84. While increasing the dosage could extend the duration, it did not guarantee 12 hours of relief.

85. But, higher doses did guarantee more money for Purdue and its sales representatives, while exposing patients to greater risks of physical and psychological dependence.

86. Purdue charged wholesalers on average about $97 for a bottle of the 10-milligram pills, the smallest dosage, while the maximum strength, 80 milligrams, cost more than $630, according to 2001 sales. On information and belief, commissions and performance evaluations for the sales force were based in part on the proportion of sales from high-dose pills.

87. Purdue was aware that those on higher doses of opioids are more likely to overdose.

88. Indeed, an analysis of the medical records of more than 32,000 patients on OxyContin and other painkillers in Ontario, Canada, found that one in 32 patients on high doses fatally overdosed.

89. Purdue and the Sacklers knew that the potential for abuse was a barrier to expanding opioid sales. For example, prior to launching OxyContin, Purdue conducted focus groups with doctors and "learned that the 'biggest negative' that might prevent widespread use of the drug was ingrained concern regarding the 'abuse potential' of opioids."[19]

90. In its initial press release launching the drug, Purdue told doctors that one OxyContin tablet would provide "smooth and sustained pain control all day and all night." Based in large part on that promise, and Purdue's repeated assurances that opioids were both effective and non-addictive, OxyContin became America's bestselling painkiller.[20] But, Purdue had no evidentiary basis for these claims.

91. In truth, and as alleged above, Purdue's nationwide marketing claims were false and highly deceptive. OxyContin was not superior to immediate-release opioids. And not only does OxyContin wear off well in advance of 12 hours, as Purdue's own early studies showed, it is (contrary to Purdue's central thesis) highly addictive.

[19] Keefe, *Empire of Pain*, *supra* n.3.

[20] Press Release, Purdue Pharma L.P., New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain (May 31, 1996); see also, http://documents.latimes.com/oxycontin-press-release-1996/ (last visited February 20, 2018

92. "Brain abnormalities resulting from chronic use of heroin, oxycodone, and other morphine-derived drugs are underlying causes of opioid dependence (the need to keep taking drugs to avoid a withdrawal syndrome) and addiction (intense drug craving and compulsive use)."[21]

93. Furthermore, contrary to what Purdue was telling doctors, experts characterized the 12-hour dosing regimen as "'an addiction producing machine.'"[22] Purdue had reportedly known for decades that it falsely promised 12-hour relief and nevertheless mobilized hundreds of sales representatives to "refocus" physicians on 12-hour dosing:

- . . . ***Even before OxyContin went on the market, clinical trials showed many patients weren't getting 12 hours of relief***. Since the drug's debut in 1996, the company has been confronted with additional evidence, including complaints from doctors, reports from its own sales representatives and independent research.

- The company has held fast to the claim of 12-hour relief, in part to protect its revenue. OxyContin's market dominance and its high price – up to hundreds of dollars per bottle – hinge on its 12-hour duration. Without that, it offers little advantage over less expensive painkillers.

- When many doctors began prescribing OxyContin at shorter intervals in the late 1990s, Purdue executives mobilized hundreds of sales representatives to "refocus" physicians on 12-hour dosing. Anything shorter "needs to be nipped in the bud. NOW!!" one manager wrote to her staff.

- Purdue tells doctors to prescribe stronger doses, not more frequent ones, when patients complain that OxyContin doesn't last 12 hours. That approach creates risks of its own. Research shows that the more potent the dose of an opioid such as OxyContin, the greater the possibility of overdose and death.

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[21] Kosten, et al., *The Neurobiology of Opioid Dependence: Implications for Treatment*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2851054/

[22] Ryan, *Description of Hell*, supra n. 16.

- More than half of long-term OxyContin users are on doses that public health officials consider dangerously high, according to an analysis of nationwide prescription data conducted for The Times.[23]

94. As reported by *The New York Times*, "internal Purdue Pharma documents show that company officials recognized even before the drug was marketed that they would face stiff resistance from doctors who were concerned about the potential of a high-powered narcotic like OxyContin to be abused by patients or cause addiction." To combat this resistance, Purdue falsely promised the long-acting, extended-release formulation was safer and "less prone to such problems."[24]

B. Purdue & Abbott Laboratories Co-Promotion of OxyContin

95. Purdue and Abbott entered into a co-promotion agreement to market and sell OxyContin from 1996 through 2002—a critical period directly following the approval of the drug by the U.S. Food and Drug Administration.

96. With Abbott's help, sales of OxyContin went from a mere $49 million in its first full year on the market to $1.6 billion in 2002. Over the life of the partnership, Purdue paid Abbott at least $374 million.

97. The sales teams of Purdue and Abbott worked together -- holding regular strategy sessions, alternating meeting locations between Purdue's Stamford, Conn., headquarters and Abbott's corporate offices in Illinois.

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[23] Ryan, *Description of Hell*, *supra* n. 16.

[24] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. Times (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html (hereinafter "Meier, *Guilty Plea*").

98. Indeed, an Abbott executive wrote to Purdue's vice president of marketing pledging to take the relationship between the companies to "new heights with our positioning of OxyContin as a key component of Abbott Pain Management."

99. Abbott heavily incentivized its sales staff to push OxyContin, offering $20,000 cash prizes and luxury vacations to top performers.

100. While marketing a highly dangerous and addictive drug, the sales team cavalierly used terminology from the Crusades: Sales representatives were called "royal crusaders" and "knights" in internal documents, and they were supervised by the "Royal Court of OxyContin" — executives referred to in memos as the "Wizard of OxyContin," "Supreme Sovereign of Pain Management," and the "Empress of Analgesia." The head of pain care sales, Jerry Eichhorn, was the "King of Pain" and signed memos simply as "King."

101. Abbott sales staff was instructed that if a doctor was concerned about the euphoria a patient was experiencing on the shorter-acting painkiller Vicodin, they should tell the physician, "OxyContin has fewer such effects."

102. Abbott also instructed sales representatives to highlight the "less abuse/addiction potential" of the drug, which could be taken just twice a day because of its time-release formulation.

103. Abbott sales representatives were also given a graphic to show doctors that depicted levels of its pain-killing ingredient in the bloodstream holding steady, but, on information and belief, the graphic mislead physicians to believe that the levels were "steadier" or "flatter" than they actually were.

104. And a "coaching sheet" prepared for Abbott sales personnel advised discussing the potential abuse of OxyContin only if a doctor brought it up, and to tell physicians that it was "street users" who were misusing the drug, rather than "true pain patients."

105. On information and belief, under the agreement with Purdue, Abbott received 25 percent of all net sales, up to $10 million, for prescriptions written by doctors its sales representatives called on, and 30 percent of sales above $10 million, according to court records.

106. On information and belief, prescriptions written by "Abbott MD's" comprised 25 percent of all OxyContin prescriptions, and between 1996 and 2002, Abbott was paid more than $374 million in commissions.

107. Even after Abbott stopped selling OxyContin, it received a residual payment of 6 percent of net sales of OxyContin by Purdue.

1. Purdue Used Big Data to Optimize Overprescribing.

108. On information and belief, for years Purdue has compiled profiles of doctors and their prescribing habits into databases.

109. These databases organized the information based on location to indicate the spectrum of prescribing patterns in a given state or county.

110. Armed with this sensitive data, Purdue's sales representatives could determine which doctors they would target to sell OxyContin to and which populations were susceptible to its product.

111. Indeed, Purdue's databases contained information of hundreds of doctors suspected of recklessly prescribing OxyContin to addicts and drug dealers, but Purdue did not timely alert law enforcement or medical authorities.

112. In other words, Purdue, through its use of big data had a window to see where OxyContin was being prescribed and recklessly overprescribed. And, rather than putting a stop to it, simply pushed more pills in that direction.

2. OxyContin Opens a New Product Category for Big Pharma.

113. Purdue's marketing of OxyContin transformed the practice of medicine. Other drug companies began peddling their own narcotic painkillers for routine injuries all based on the twin falsities that these powerful narcotics were not addictive and were safe and effective treatments for routine pain.

114. By 2010, one out of every five doctor's visits in the U.S. for pain resulted in a prescription for narcotic painkillers, according to a Johns Hopkins University study.

C. The Manufacturer Defendants Misled the Public Regarding the Dangers of Opioid Addiction and the Efficacy of Opioids for Long-Term Use, Causing Sales and Rates of Overdose and Addiction to Soar

115. From the mid-90s to the present, the Manufacturer Defendants aggressively marketed and falsely promoted opioids as presenting little to no risk of addiction, even when used long term for chronic pain. They infiltrated medical academia faculty and literature as well as regulatory agencies to convince doctors that treating chronic pain with long-term opioids was evidence-based medicine when, in fact, it was not. Huge prescribing and profits resulted from these efforts, leading to the present addiction and overdose epidemic.

1. Background on Opioid Overprescribing

116. The Manufacturer Defendants' scheme to drive their rapid and dramatic expansion of prescription opioids relied on the misuse of two reports. The first was a 100-word letter to the

editor published in 1980 in the *New England Journal of Medicine* ("1980 Letter to the Editor").[25]

A 2017 study in the *New England Journal of Medicine* concluded:

> that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy.[26]

117. Second was a single retrospective study published by Drs. Russell Portenoy ("Portenoy") and Kathleen Foley ("Foley") ("Portenoy Publication").[27] Portenoy, one of the industry's most vocal advocates for long-term opioid use, made it his life's work to campaign for the movement to increase use of prescription opioids. He was one of Opioid manufacturer's paid

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[25] The 1980 Letter to the Editor, by Jane Porter ("Porter") and Dr. Herschel Jick ("Jick"), reported that less than 1% of patients at Boston University Medical Center who received narcotics while hospitalized became addicted. Jane Porter & Hershel Jick, *Addiction rate in patients treated with narcotics*, 302(2) New Eng. J. Med. 123 (Jan. 10, 1980). The letter did not support the conclusion for which it was often cited by the industry. Harrison Jacobs, *This one-paragraph letter may have launched the opioid epidemic*, Bus. Insider (May 26, 2016), http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-016-5 (hereinafter "Jacobs, *One-paragraph letter*"). As discussed in a 2009 article in the *American Journal of Public Health*, the 1980 Letter to the Editor "shed[] some light on the risk of addiction for acute pain, [but did] not help establish the risk of iatrogenic addiction when opioids are used daily for a prolonged time in treating chronic pain. [Indeed, t]here are a number of studies . . . that demonstrate that in the treatment of chronic non-cancer-related pain with opioids, there is a high incidence of prescription drug abuse." Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am. J. Pub. Health 221-27 (Feb. 2009).

[26] http://www.nejm.org/doi/full/10.1056/NEJMc1700150.

[27] In 1986, the medical journal *Pain*, which would eventually become the official journal of the American Pain Society ("APS"), published an article by Portenoy and Foley summarizing the results of a "study" of 38 chronic non-cancer pain patients who had been treated with opioid painkillers. Portenoy and Foley concluded that, for non-cancer pain, opioids "can be safely and effectively prescribed to selected patients with relatively little risk of producing the maladaptive behaviors which define opioid abuse." However, their study was neither scientific nor did it meet the rigorous standards commonly used to evaluate the validity and strength of such studies in the medical community. For instance, the study was not a prospective, and had no placebo control group—essentially, the authors queried a few dozen patients about their prior experiences with opioid treatment. The authors themselves advised caution, stating that the drugs should be used as an "alternative therapy" and recognizing that longer-term studies of patients on opioids would have to be performed. None were. *See* Russell K. Portenoy & Kathleen M. Foley, *Chronic use of opioid analgesics in non-malignant pain: report of 38 cases*, 25(2) Pain 171-86 (May 1986).

"thought leaders" and was paid to travel the country to promote more liberal opioid prescribing for many types of pain. His talks were sponsored by the Manufacturer Defendants and organizations paid by them as continuing medical education ("CME") programs for doctors. He had financial relationships with at least a dozen pharmaceutical companies, most of which produced prescription opioids.[28]

118. Portenoy has now admitted that he minimized the risks of opioids. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not "real" and, in fact, left real evidence behind:

> I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, ***none of which represented real evidence***, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information *in toto* and feel more comfortable about opioids in a way they hadn't before. ***In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind***.[29]

119. The damage, however, was already done. Remarkably, the Manufacturer Defendants used these two publications, the 1980 Letter to the Editor and the Portenoy Publication, as the foundation for a massive, far-reaching campaign to dramatically shift the thinking of healthcare providers, patients, policymakers and the public on the risk of addiction presented by opioids.

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[28] Anna Lembke (2016), *Drug Dealer, MD – How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop*, at 59 (citing Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* (St. Martin's Press, 1st ed. 2003)).

[29] Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), https://www.youtube.com/watch?v=DgyuBWN9D4w.

120. In 1997, the APS and the American Academy of Pain Medicine ("AAPM") (both funded by the Manufacturer Defendants) issued a "landmark consensus," co-authored by Portenoy, stating there is little risk of addiction or overdose in pain patients.[30]

121. Despite the prescription opioids' highly addictive qualities, the Manufacturer Defendants aggressive pro-opioid marketing efforts effected a dramatic shift in the public's and prescribers' perception of the safety and efficacy of opioids for chronic long-term pain and everyday use. Contrary to what doctors had previously understood about opioid risks and benefits, they were encouraged for the last two decades by the Manufacturer Defendants to prescribe opioids aggressively and were assured, based on false evidence provided directly by the Manufacturer Defendants and numerous medical entities funded by or related to the Manufacturer Defendants (and others with financial interests in generating more opioid prescriptions), that: (i) the risk of becoming addicted to prescription opioids among patients being treated for pain was low, even as low as less than 1%; and (ii) great harm was caused by "under-treated pain." These two foundational falsehoods led directly to the current opioid crisis.

122. As described in more detail below, the essence of the scheme was to redefine back pain, neck pain, headaches, arthritis, and other common conditions suffered by most of the population at some point in their lives as a distinct malady – chronic pain – that doctors and patients should take seriously and for which opioids were an appropriate, successful, and low-risk treatment.

[30] Jacobs, *One-paragraph letter*, *supra* n.23.

123. The scheme was tragically successful. Indeed, studies now show more than 85% of patients taking OxyContin at common doses are doing so for chronic non-cancer related pain.[31]

124. This false and misleading marketing strategy continued despite studies revealing that up to 56% of patients receiving long-term prescription opioid painkillers for chronic back pain progress to addictive opioid use, including patients with no prior history of addiction.[32]

125. Thus, based on false and incomplete evidence, the Manufacturer Defendants expanded their market exponentially from patients with end-stage cancer and acute pain, an obviously limited customer base, to anyone suffering from "chronic pain," which by some accounts includes approximately 100 million Americans – nearly one-third of the country's population.[33] The treatment of chronic pain includes patients whose general health is good enough to refill prescriptions month after month, year after year.

126. The promotion, distribution (without reporting suspicious sales) and rampant sale of opioids for such treatment has made defendants billions of dollars. It has also led to the opioid addiction and overdose crisis in the County and throughout the Country.

2. The Fraudulent Sales Practices

127. As set forth below, the Manufacturer Defendants employed a variety of strategies both to normalize the use of opioids for chronic long-term pain and to misrepresent the very significant risk of abuse, addiction, overdose, and death.

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[31] Harriet Ryan, *et al.*, *"OxyContin goes global – 'We're only just getting started'"*, L.A. Times (December 18, 2016), http://www.latimes.com/projects/la-me-oxycontin-part3/ (hereinafter "Ryan, *OxyContin goes global*").

[32] Lembke (2016), *supra* n.26, at 22 (citing Martell, *et al.*, *Systematic review: opioid treatment for chronic back pain: prevalence, efficacy and association with addiction*, 146(2) Ann. Intern. Med. 116-27 (2007).

[33] *AAPM Facts and Figures on Pain*, The American Academy of Pain Medicine, http://www.painmed.org/patientcenter/facts_on_pain.aspx#refer (last visited February 20, 2018).

a. The Manufacturer Defendants Funded Front Organizations that Published and Disseminated False and Misleading Marketing Materials

128. Defendants sponsored purportedly neutral medical boards and foundations that educated doctors and set guidelines for the use of opioids in medical treatment in order to promote the liberal prescribing of opioids for chronic pain. The following organizations, funded by the Manufacturer Defendants, advised doctors that liberal prescribing of opioids was both safe and effective. In truth, it was neither safe, nor effective.

129. **Federation of State Medical Boards**: The Federation of State Medical Boards ("FSMB") is a trade group representing the 70 medical and osteopathic boards in the United States. The FSMB develops guidelines that serve as the basis for model policies with the stated goal of improving medical practice. Defendants Purdue, Cephalon and Endo have provided substantial funding to the FSMB.

130. In 2007, the FSMB printed and distributed a physician's guide on the use of opioids to treat chronic pain titled "Responsible Opioid Prescribing" by Dr. Scott M. Fishman ("Fishman"). After the guide was adopted as a model policy, the FSMB reportedly asked Purdue for $100,000 to help pay for printing and distribution. FSMB disseminated the guide to ***700,000*** practicing doctors.

131. The guide's clear purpose is to deceive prescribers regarding the purported under-treatment of pain and falsely assure them that opioid therapy is an appropriate treatment for chronic, non-cancer pain:

- Pain management is integral to good medical practice and for all patients;
- ***Opioid therapy to relieve pain and improve function is a legitimate medical practice for*** acute and ***chronic pain of*** both cancer and ***non-cancer origins***;

- ***Patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient***.

* * *

Four key factors contribute to the ongoing problem of under-treated pain:

1. Lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment;

2. The perception that prescribing adequate amounts of opioids will result in unnecessary scrutiny by regulatory authorities;

3. ***Misunderstanding of addiction and dependence***; and

4. Lack of understanding of regulatory policies and processes.

132. The guide also purports to offer "professional guidelines" that will "easily and efficiently" allow physicians to manage that risk and "minimize the potential for abuse." Indeed, it states that even for those patients assessed to have risk of substance abuse, "it does not mean that opioid use will become problematic or that opioids are contraindicated," just that physicians should use additional care in prescribing.

133. The guide further warns physicians to "[b]e aware of the distinction between pseudo addiction and addiction" and teaches that behaviors such as "[r]equesting [drugs] by name," "[d]emanding or manipulative behavior," "[o]btaining opioid drugs from more than one physician" and "[h]oarding opioids," these are just signs of "pseudoaddiction."

134. It defines "Physical Dependence" as an acceptable result of opioid therapy not to be equated with addiction and states that while "[i]t may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications," there could be other acceptable reasons for non-adherence.

135. The guide, which became the seminal authority on opioid prescribing for the medical profession, dramatically overstated the safety and efficacy of opioids and understated the risk of opioid addiction.

136. This heightened focus on the under-treatment of pain was a concept designed by the Manufacturer Defendants to sell opioids. ***The FSMB actually issued a report calling on medical boards to punish doctors for inadequately treating pain***.[34] Among the drafters of this policy was Dr. J. David Haddox ("Haddox").

137. Haddox coined the term "pseudoaddiction," which wholly lacked scientific evidence but quickly became a common way for the Manufacturer Defendants and their allies to promote the use of opioids even to patients displaying addiction symptoms.

138. Haddox later became a Purdue Vice President.[35] At a 2003 conference at Columbia University he said: "If I gave you a stalk of celery and you ate that, it would be healthy. But if you put it in a blender and tried to shoot it into your veins, it would not be good."[36]

139. In 2012 and again in 2017, the guides and the sources of their funding became the subject of a Senate investigation.

140. On June 8, 2012, the FSMB submitted a letter to the U.S. Senate Committee on Finance ("Senate Finance Committee") concerning its investigation into the abuse and misuse of

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[34] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, at A1.

[35] Gounder, *Who is Responsible for the Pail-Pill Epidemic?,* The New Yorker (Nov. 8, 2013) (hereinafter, *Who is Responsible*).

[36] Keefe, *Empire of Pain*, *supra* n.3.

opioids.[37] While the letter acknowledged the escalation of drug abuse and related deaths resulting from prescription painkillers, the FSMB continued to focus on the "serious and related problem" that "[m]illions of Americans suffer from debilitating pain – a condition that, for some, can be relieved through the use of opioids." Among other things, the letter stated, "Studies have concluded that both acute pain and chronic pain are often under-treated in the United States, creating serious repercussions that include the loss of productivity and quality of life." The letter cited no such studies. The letter also confirmed that the FSMB's "Responsible Opioid Prescribing: A Physician's Guide" has been distributed in each of the 50 states and the District of Columbia.

141. In addition, the FSMB letter disclosed payments the FSMB received from organizations that develop, manufacture, produce, market or promote the use of opioid-based drugs from 1997 through the present, including in the payments received are the following payments from Defendants:

[37] June 8, 2012 Letter from Federation of State Medical Boards to U.S. Senators Max Baucus and Charles Grassley.

Company	Fiscal Year	Amount
Purdue	2001	$38,324.56
	2002	$10,000.00
	2003	$85,180.50
	2004	$87,895.00
	2005	$244,000.00
	2006	$207,000.00
	2007	$50,000.00
	2008	$100,000.00
	Total Purdue Payments	$822,400.06
Endo	2007	$40,000.00
	2008	$100,000.00
	2009	$100,000.00
	2011	$125,000.00
	2012	$46,620.00
	Total Endo Payments	$371,620.00
Cephalon	2007	$30,000.00
	2008	$100,000.00
	2011	$50,000.00
	Total Cephalon Payments	$180,000.00
Mallinckrodt	2011	$100,000.00
	Total Mallinckrodt Payments	$100,000.00

142. The letter also disclosed payments of $40,000 by Endo and $50,000 by Purdue to directly fund the production of "Responsible Opioid Prescribing."

143. **The Joint Commission**: The Joint Commission is an organization that establishes standards for treatment and accredits healthcare organizations in the United States. The Manufacturer Defendants, including Purdue, contributed misleading and groundless teaching materials and videos to the Joint Commission, which emphasized what Big Pharma coined the "under-treatment of pain," referenced pain as the "fifth vital sign" (the first and only unmeasurable/subjective vital sign) that must be monitored and treated, and encouraged the use of prescription opioids for chronic pain while minimizing the danger of addiction. It also called doctors' concerns about addiction "inaccurate and exaggerated."

144. In 2000, the Joint Commission printed a book for purchase by doctors as part of required continuing education seminars that cited studies claiming "***there is no evidence that addiction is a significant issue when persons are given opioids for pain control***." The book was sponsored by Purdue.

145. In 2001, the Joint Commission and the National Pharmaceutical Council (founded in 1953 and supported by the nation's major pharmaceutical companies[38]) collaborated to issue a 101-page monograph titled "Pain: Current understanding of assessment, management, and treatments." The monograph states falsely that beliefs about opioids being addictive are "erroneous":

> ***Societal issues that contribute to the undertreatment of pain include drug abuse programs and erroneous beliefs about tolerance, physical dependence, and addiction*** (*see* I.E.5). ***For example, some clinicians incorrectly assume that exposure to an addictive drug usually results in addiction***.
>
> * * *
>
> **b. Etiology, issues, and concerns**
>
> Many medications produce tolerance and physical dependence, and some (*e.g.*, opioids, sedatives, stimulants, anxiolytics, some muscle relaxants) may cause addiction in vulnerable individuals. Most experts agree that ***patients who undergo prolonged opioid therapy usually develop physical dependence but do not develop addictive disorders. In general, patients in pain do not become addicted to opioids. Although the actual risk of addiction is unknown, it is thought to be quite low***. A recent study of opioid analgesic use revealed "low and stable" abuse of opioids between 1990 and 1996 despite significant increases in opioids prescribed. . . .
>
> ***Fear of causing addiction (i.e., iatrogenic addiction), particularly with opioid use, is a major barrier to appropriate pain management. This fear sometimes reflects a lack of understanding of the risk of addiction with therapeutic drug use. Although studies suggest that the risk of iatrogenic***

[38] Currently funded by Johnson & Johnson, Purdue and Teva, among others.

> ***addiction is quite low*** (e.g., Perry and Heidrich, Zenz et al.), ***surveys indicate that clinicians often overestimate this risk***.[39]

146. Additionally, the monograph recommends that "[p]ain . . . is assessed in all patients" and suggests that long-acting (*i.e.*, extended release) pain medications are superior and should be used whenever possible:

> ***Long-acting and sustained-release opioids are useful for patients with continuous pain, as they lessen the severity of end-of-dose pain*** and often allow the patient to sleep through the night.
>
> * * *
>
> - Administer opioids primarily via oral or transdermal routes, using long-acting medications when possible.[40]

147. As alleged above, however, such medications do not last as long as promised, and, contrary to the monograph's claims, addiction risk is very high.

148. The Manufacturer Defendants' infiltration and influence over the Joint Commission's standards and literature provided doctors with misleading information under the guise of objectivity.

149. Further, as more and more doctors migrated from private practice to integrated healthcare systems in the 2000s, treatment options were dictated by, among other things, the Joint Commission's guidelines.[41] Consistent with the guidelines, doctors who left pain untreated were viewed as demonstrating poor clinical skills and/or being morally compromised.[42]

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[39] *Pain: Current Understanding of Assessment, Management, and Treatments* 16-17 (Dec. 2001), http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf (footnotes and citations omitted).

[40] *Id*. at 38, 68 (Table 38).

[41] Lembke (2016), *supra* n.26, at 119.

[42] *Id*. at 42.

150. The U.S. General Accounting Office's December 2003 Report to Congressional Requesters confirms that Purdue funded the "pain management educational courses" that taught the new standard of care for treating pain. It further revealed that Purdue disseminated educational materials on pain management, which "'facilitated [Purdue's] access to hospitals to promote OxyContin.'"[43]

151. **American Pain Foundation**: The American Pain Foundation ("APF"), headquartered in Baltimore, Maryland, describes itself as the nation's largest organization for pain patients.[44] While APF holds itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from defendants Purdue, Endo, Janssen and Cephalon.

152. In fact, it received more than $10 million in funding from opioid manufacturers from 2007 to 2012, when it shut down days after the Senate Finance Committee launched an investigation of APF's promotion of prescription opioids.

153. The APF's guides for patients, journalists, and policymakers downplayed the risk of addiction and greatly exaggerated the benefits associated with opioid painkillers. [45]

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[43] *Supra, Who Is Responsible*, *supra* n.35; U.S. General Accounting Office, GAO-04-110, *Prescription Drugs, OxyContin Abuse and Diversion and Efforts to Address the Problem* (Dec. 2003), http://www.gao.gov/new.items/d04110.pdf).

[44] The APF was the focus of a December investigation by ProPublica in the *Washington Post* that detailed its close ties to drugmakers.

[45] Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012, 8:57 PM), https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups (hereinafter "Ornstein, *American Pain Foundation*").

154. For example, in 2001, APF published "Treatment Options: A Guide for People Living with Pain."[46] The guide, which was produced due to support from companies including defendants Cephalon and Purdue, misrepresented the risks associated with opioid use. Among other things, the guide:

- lamented that opioids were sometimes called narcotics because "***[c]alling opioid analgesics 'narcotics' reinforces myths and misunderstandings*** as it places emphasis on their potential abuse rather than on the importance of their use as pain medicines";[47]
- stated that "[o]pioids are an essential option for treating ***moderate*** to severe pain associated with surgery or trauma";[48] and
- opined that "[r]estricting access to the most effective medications for treating pain [opioids] is not the solution to drug abuse or addiction."[49]

155. Portenoy is quoted in the guide as saying "[t]his is a very good resource for the pain patient," and Fishman, who is quoted as saying, "[w]hat a great job! Finally, a pill consumer resource created for patients with pain. A 'must have' for every physician's waiting room."[50]

156. In 2003, APF published a newsletter titled "Best of . . . The Pain Community News" that purported to clarify any confusion over addiction and opioids and emphasized the "tragic consequence of leaving many people with severe pain under-treated because they – or their doctors – fear that opioids will cause addiction."

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[46] *Treatment Options: A Guide for People Living with Pain*, American Pain Foundation, https://assets.documentcloud.org/documents/277605/apf-treatment options.pdf.

[47] *Id*. at 11.

[48] *Id*.

[49] *Id*. at 15.

[50] *Id*. at 76.

157. In 2009, Endo sponsored APF's publication and distribution of "Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families" ("Exit Wounds"), a book described as "the inspirational story of how one courageous veteran, with the aid of his family, recovered and thrived despite near death, traumatic brain injury, and the loss of a limb." It also purported to "offer[] veterans and their families comprehensive and authoritative information on . . . treatment options, and strategies for self-advocating for optimal pain care and medical resources inside and outside the VA system."[51]

158. Among other false statements, Exit Wounds reported: "Long experience with opioids shows that ***people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications***."

159. Endo, through APF, thus knowingly distributed false information to veterans with the intention that they would "self-advocat[e]" for opioids. This publication also omits a discussion of the risks associated with opioid use.

160. In 2009, APF played a central role in a first-of-its-kind web-based series called "Let's Talk Pain," hosted by veteran TV journalist Carol Martin. The series brought together healthcare providers and "people with pain to discuss a host of issues from managing health care for pain to exploring integrative treatment approaches to addressing the psychological aspects associated with pain." The "Let's Talk Pain" talk show is still available online. In the very first episode of this talk show, the following exchange took place:

> [**Teresa Shaffer (APF Action Network Leader)**:] As a person who has been living with pain for over 20 years, opioids are a big part of my pain treatment. And I have been hearing such negative things about opioids and the risk factors of opioids. Could you talk with me a little bit about that?

[51] Press Re http://www.vmwusa.org/index.php/component/content/article/62-vmwnow/504-exitwounds

> [**Dr. Al Anderson (AAPM Board of Directors)**:] The general belief system in the public is that the opioids are a bad thing to be giving a patient. Unfortunately, it's also prevalent in the medical profession, so patients have difficulty finding a doctor ***when they are suffering from pain for a long period of time***, especially ***moderate*** to severe pain. And ***that's the patients that we really need to use the opioids*** methods of treatment, because they are the ones who need to have some help with the function and they're the ones that need to be controlled enough so that they can increase their quality of life.[52]

161. In reality, there is little scientific evidence to support the contention that opioids taken long-term improve function or quality of life for chronic pain patients.[53] To the contrary, there is ample evidence that opioids impose significant risks and adverse outcomes on long-term users and may actually reduce function.[54] As a recent article in the *New England Journal of Medicine* concluded: "Although opioid analgesics rapidly relieve many types of acute pain and improve function, the benefits of opioids when prescribed for chronic pain are much more questionable."

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[52] *Episode 1: Safe Use of Opioids (PainSAFE)*, Let's Talk Pain (Sept. 28, 2010), https://www.youtube.com/watch?v=zeAIvAMRgsk.

[53] Lembke (2016), *supra* n.26, at 59 (citing *Agency for Healthcare Research and Quality (US): The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain*, Evid. Rep./Tech. Assess., No. 218 (2014), https://ahrq-ehc-application.s3.amazonaws.com/media/pdf/chronic-pain-opioid-treatment-research.pdf).

[54] Discussing the "March 2016 Guideline for Prescribing Opioids for Chronic Pain" by the Centers for Disease Control ("CDC"), doctors wrote:

> Most placebo-controlled, randomized trials of opioids have lasted 6 weeks or less, and we are aware of no study that has compared opioid therapy with other treatments in terms of long-term (more than 1 year) outcomes related to pain, function, or quality of life. The few randomized trials to evaluate opioid efficacy for longer than 6 weeks had consistently poor results. In fact, several studies have showed that use of opioids for chronic pain may actually worsen pain and functioning, possibly by potentiating pain perception.

Thomas Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501-04 (Apr. 21, 2016), http://www.nejm.org/doi/full/10.1056/NEJMp1515917?af=R&rss=currentIssue&#t= article.

162. The APF also developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website called www.painknowledge.org. NIPC promoted itself as an education initiative and promoted its expert leadership team, including purported experts in the pain management field. The website painknowledge.org promised that, on opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. In a brochure available on painknowledge.org titled "Pain: Opioid Facts," the NIPC misled that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted" and even refused to rule out the use of opioid pain relievers for patients who have a history of addiction to opioids.[55]

163. In or around 2011, the APF published the "Policymaker's Guide," sponsored by Purdue, which dispelled the notion that "strong pain medication leads to addiction" by characterizing it as a "***common misconception***[]":

> ***Many people living with pain, and even some health care practitioners, falsely believe that opioid pain medicines are universally addictive***. As with any medication, there are risks, but these risks can be managed when these medicines are properly prescribed and taken as directed. For more information about safety issues related to opioids and other pain therapies, visit http://www.painsafe.org.[56]

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[55] *Pain: Opioid Facts*, Pain Knowledge, https://www.peacehealthlabs.org/lab-services/Laboratory%20Services%20Documents/PtProtect/Opioid%20Facts.pdf (last visited February 20, 2018).

[56] *A Policymaker's Guide to Understanding Pain & Its Management*, American Pain Foundation at 5, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last visited February 20, 2018).

164. The guide describes "pain in America" as "an evolving public health crisis" and characterizes concerns about opioid addiction as misconceptions: "Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include: . . . ***Misconceptions about opioid addiction***."[57] It even characterizes as a "***myth***" that "***[c]hildren can easily become addicted to pain medications***."[58] The guide further asserts that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health and health-related quality of life for chronic pain patients, which was not the case.[59]

165. In December 2011, the *Washington Post* reported on ProPublica's investigation of the APF, which detailed APF's close ties to drugmakers:

> ***[T]he pills continue to have an influential champion in the American Pain Foundation***, which describes itself as the nation's largest advocacy group for pain patients. ***Its message: The risk of addiction is overblown, and the drugs are underused***.
>
> ***What the nonprofit organization doesn't highlight is the money behind that message.***

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[57] *Id*. at 6.

[58] *Id*. at 40.

[59] The "Policymaker's Guide" cites for support "Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects," a review published in 2006 in the *Canadian Medical Association Journal*. *Id*. at 34. However, the review concludes: "For functional outcomes, ***the other analgesics were significantly more effective than were opioids***." Andrea D. Furlan, *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Canadian Med. Assoc. J. 1589-94 (May 23, 2006), https://www.ncbi.nlm.nih.gov/ pmc/articles/PMC1459894/. The Purdue-sponsored guide failed to disclose both this conclusion and the fact that the review analyzed studies that lasted, on average, five weeks and therefore could not support the long-term use of opioids.

> ***The foundation collected nearly 90 percent of its $5 million in funding last year from the drug and medical-device industry – and closely mirrors its positions***, an examination by ProPublica found.[60]

166. **American Academy of Pain Medicine and American Pain Society**: The Manufacturer Defendants, including at least Endo, Janssen and Purdue, have contributed funding to the AAPM and the APS for decades.

167. In 1997, the AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The chairman of the committee that issued the statement, Haddox, was, at the time, a paid speaker for Purdue. Haddox was later hired as Purdue's vice president for health policy. The consensus statement, which also formed the foundation of the 1998 guidelines, was published on the AAPM's website. AAPM's corporate council includes Purdue, Depomed, Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Fishman (2005), Dr. Perry G. Fine ("Fine") (2011) and Lynn R. Webster ("Webster") (2013), all of whose connections to the opioid manufacturers are well-documented.

168. At or about the same time, the APS introduced the "pain as the 5th vital sign" campaign.

169. AAPM and APS issued guidelines in 2009 ("2009 Guidelines") that continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines received funding from defendants Janssen, Cephalon, Endo, or Purdue.

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[60] Charles Ornstein & Tracy Weber, *Patient advocacy group funded by success of painkiller drugs, probe finds*, Wash. Post (Dec. 23, 2011), https://www.washingtonpost.com/national/health-science/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probe-finds/2011/12/20/gIQAgvczDP_story.html?utm_term=. 22049984c606.

170. The 2009 Guidelines falsely promoted opioids as safe and effective for treating chronic pain and concluded that the risk of addiction was manageable for patients regardless of past abuse histories.[61] The 2009 Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians but also the body of scientific evidence on opioids; they were reprinted in the journal Pain, have been cited hundreds of times in academic literature and remain available online. The Manufacturer Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions.

171. **Alliance for Patient Access ("APA")**: Founded in 2006, APA is a self-described patient advocacy and health professional organization that styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care."[62] It is run by Woodberry Associates, a lobbying firm that was also established in 2006.[63] As of June 2017, the APA listed 30 "Associate Members and Financial Supporters." The list includes defendants Endo, Johnson & Johnson, Mallinckrodt, Purdue, and Cephalon.

172. APA's board members have also directly received substantial funding from pharmaceutical companies.[64] For instance, board vice president Srinivas Nalamachu, M.D., who

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[61] Roger Chou, *et al*., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non- Cancer Pain*, 10(2) J. Pain 113 (Feb. 2009), http://www.jpain.org/article/S1526-5900(08)00831-6/pdf (hereinafter "Chou, *Clinical Guidelines*").

[62] THE ALLIANCE FOR PATIENT ACCESS, *About AfPA*, http://allianceforpatientaccess.org/about-afpa/#membership (last visited February 20, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

[63] Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma's agenda*, Health News Review (Oct. 2, 2017), https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/.

[64] All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica's Dollars for Docs database, *available at* https://projects.propublica.org/docdollars/.

practices in Kansas, received more than $800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids' side-effects, including from defendants Endo, Insys, Purdue, and Cephalon. Dr. Nalamachu's clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys.[65] Other board members include Dr. Robert A. Yapundich from North Carolina, who received $215,000 from 2013 through 2015 from pharmaceutical companies, including payments by defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than $240,000 between 2013 and 2015 from pharmaceutical companies including defendants Endo, Mallinckrodt, and Cephalon; Dr. Howard Hoffberg from Maryland, who received $153,000 between 2013 and 2015 from pharmaceutical companies including defendants Endo, Purdue, Insys, Mallinckrodt, and Cephalon; and Dr. Robin K. Dore from California, who received $700,000 between 2013 and 2015 from pharmaceutical companies.

173. Among its activities, APA issued a white paper titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse."[66] Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

> Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.

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[65] Andy Marso, *FBI seizes records of Overland Park pain doctor tied to Insys*, Kansas City Star (July 20, 2017), http://www.kansascity.com/news/business/health-care/article162569383.html.

[66] *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, Institute for Patient Access (Oct. 2013), http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf.

* * *

> In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives.

* * *

> . . . . We cannot merely assume that these programs will reduce prescription pain medication use and abuse.

174. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

> Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.

175. In addition, in an echo of earlier industry efforts to push back against what they termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication:

> Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management – a situation fueled by the numerous regulations and fines that surround prescription pain medications.

176. In conclusion, the white paper states that "Prescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery,

afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs."

b. The Manufacturer Defendants Paid Doctors and Key Opinion Leaders, and Sponsored Speakers' Bureaus to Disseminate False and Misleading Messaging

177. The Manufacturer Defendants have paid millions of dollars to physicians to promote aggressive prescribing of opioids for chronic pain. Recently released federal data shows that the Manufacturer Defendants increased such payments to physicians who treat chronic pain even while the opioid crisis accelerated and overdose deaths from prescription opioids and related illicit drugs, such as heroin, soared to record rates.[67] These payments come in the form of consulting and speaking fees, free food and beverages, discount coupons for drugs and other gifts. The total payments from the Manufacturer Defendants to doctors related to opioids doubled from 2014 to 2015.

178. According to experts, research shows even small amounts of money can have large effects on doctors' prescribing practices.[68] Physicians who are high prescribers are more likely to be invited to participate in defendants' speakers' bureaus. According to a study published by the U.S. National Institutes of Health, "[i]n the speakers' bureau system, physicians are recruited and trained by pharmaceutical, biotechnology, and medical device companies to deliver information about products to other physicians, in exchange for a fee."[69]

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[67] Joe Lawlor, *Even amid crisis, opioid makers plied doctors with perks*, Portland Press Herald (Dec. 25, 2016), http://www.pressherald.com/2016/12/25/even-amid-crisis-opioid-makers-plied-doctors-with-perks/.

[68] *Id*.

[69] Lynette Reid & Matthew Herder, *The Speakers' bureau system: a form of peer selling*, 7(2) Open Med. e31-e39 (Apr. 2, 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3863750/.

179. The use of speakers' bureaus has led to substantial ethical concerns within the medical field. According to a 2013 publication by the Institute on Medicine as a Profession, speakers' bureaus are ethically compromised because they often present information as objective when it is heavily biased toward the interests of the industry sponsor and, in fact, may lead to the dissemination of false or biased information. These findings are substantiated by citations to research in the *Journal of the American Medical Association*, *The Journal of Law, Medicine & Ethics* and *Academic Psychiatry*.

> **The Problem:**
>
> ***Pharmaceutical companies often recruit physicians to perform speeches or presentations for the purpose of marketing a specific drug. In 2010, 8.6% of physicians reported having received payments for participating in speakers' bureaus***. These speakers' bureaus leverage the credibility of physicians in order to promote the use of pharmaceutical products. ***The physicians are generally trained to present a certain message, or are provided with pre-produced slides. The audience may assume that these presentations are objective, when in fact they are heavily biased towards the interests of the industry sponsor***.
>
> ***Speakers' bureaus may lead to the dissemination of false or biased information.*** Exposure to industry-sponsored speaking events is associated with decreased quality of prescribing. Additionally, the compensation provided for these engagements may influence the attitudes or judgment of the presenter.[70]

180. For example, Fishman is a physician whose ties to the opioid drug industry are legion. He has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received "market rate honoraria." As discussed above, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Manufacturer Defendants. He has also worked to oppose legislation

[70] *Speakers' Bureaus: Best Practices for Academic Medical Centers*, IMAP (Oct. 10, 2013), http://imapny.org/wp-content/themes/imapny/File%20Library/Best%20Practice%20 toolkits/Best-Practices_Speakers--bureaus.pdf.

requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled "Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion."[71]

181. Similarly, Fine's ties to the Manufacturer Defendants have been well documented.[72] He has authored articles and testified in court cases and before state and federal committees, and he, too, has served as president of the AAPM and argued against legislation restricting high-dose opioid prescription for non-cancer patients. Multiple videos feature Fine delivering educational talks about prescription opioids. He has also acknowledged having failed to disclose numerous conflicts of interest.

182. Fishman and Fine are only two of the many physicians whom the Manufacturer Defendants paid to present false or biased information on the use of opioids for chronic pain.

c. Senate Investigations of the Manufacturer Defendants

183. In May 2012, the Chair and Ranking Member of the Senate Finance Committee, Max Baucus (D-MT) and Chuck E. Grassley (R-IA), launched an investigation into makers of narcotic painkillers and groups that champion them. The investigation was triggered by "an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers," including popular brand names like OxyContin, Vicodin and Opana.

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[71] Scott M. Fishman, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306(13) JAMA 1445 (2011); Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 2:14 PM), https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry (hereinafter "Weber, *Two Leaders in Pain*").

[72] Id.

184. The Senate Finance Committee sent letters to Purdue, Endo and Johnson & Johnson, as well as five groups that support pain patients, physicians or research, including the APF, AAPM, APS, University of Wisconsin Pain & Policy Studies Group and the Center for Practical Bioethics. Letters also went to the FSMB and the Joint Commission.

185. The Senators' letter to APF, the Senators addressed the magnitude of the epidemic and asserted that mounting evidence supports that the pharmaceutical companies may be responsible:

> ***It is clear that the United States is suffering from an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers such as Oxycontin (oxycodone), Vicodin (hydrocodone), Opana (oxymorphone)***. According to CDC data, "more than 40% (14,800)" of the "36,500 drug poisoning deaths in 2008" were related to opioid-based prescription painkillers. Deaths from these drugs rose more rapidly, "from about 4,000 to 14,800" between 1999 and 2008, than any other class of drugs, [killing] more people than heroin and cocaine combined. ***More people in the United States now die from drugs than car accidents as a result of this new epidemic. Additionally, the CDC reports that improper "use of prescription painkillers costs health insurers up to $72.5 billion annually in direct health care costs."***
>
> * * *
>
> Concurrent with the growing epidemic, the *New York Times* reports that, based on federal data, "***over the last decade, the number of prescriptions for the strongest opioids has increased nearly fourfold, with only limited evidence of their long-term effectiveness or risks" while "[d]ata suggest that hundreds of thousands of patients nationwide may be on potentially dangerous doses***."
>
> ***There is growing evidence pharmaceutical companies that manufacture and market opioids may be responsible, at least in part, for this epidemic by promoting misleading information about the drugs' safety and effectiveness***. Recent investigative reporting from the *Milwaukee Journal Sentinel/MedPage Today* and *ProPublica* revealed extensive ties between companies that manufacture and market opioids and non-profit organizations such as the American Pain Foundation, the American Academy of Pain Medicine, the Federation of State Medical Boards, and University of Wisconsin Pain and Policy Study Group, and the Joint Commission.
>
> In a *ProPublica* story published in the *Washington Post*, the watchdog organization examined the ***American Pain Foundation, a "health advocacy" organization that***

> ***received "nearly 90 percent of its $5 million funding from the drug and medical device industry***." *ProPublica* wrote that its review of the American Pain Foundation's "guides for patients, journalists, and policymakers ***play down the risks associated with opioids and exaggerate their benefits***. Some of the foundation's materials on the drugs include statements that are misleading or based on scant or disputed research."
>
> According to the *Milwaukee Journal Sentinel/MedPage Today*, ***a "network of national organizations and researchers with financial connections to the makers of narcotic painkillers . . . helped create a body of dubious information" favoring opioids "that can be found in prescribing guidelines, patient literature, position statements, books and doctor education courses***."
>
> Although it is critical that patients continue to have access to opioids to treat serious pain, ***pharmaceutical companies and health care organizations must distribute accurate and unbiased information about these drugs in order to prevent improper use and diversion to drug abusers***.

186. The Senators demanded substantial discovery, including payment information from the companies to various groups, including the front organizations identified above, and to physicians, including Portenoy, Fishman and Fine, among others. They asked about any influence the companies had on a 2004 pain guide for physicians that was distributed by the FSMB, on the APS' guidelines and on the APF's Military/Veterans Pain Initiative. Almost immediately upon the launch of the Senate investigation, the APF shut down "due to irreparable economic circumstances." The opioid report resulting from this investigation has not been released publicly.[73]

187. On March 29, 2017, it was widely reported[74] that yet another Senate investigation had been launched:

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[73] Paul D. Thacker, *Senators Hatch and Wyden: Do your jobs and release the sealed opioids report*, Stat News (June 27, 2016).

[74] Nadia Kounang, *Senator opens investigation into opioid manufacturers*, CNN (Mar. 29, 2017, 11:06 AM), http://www.cnn.com/2017/03/28/health/senate-opioid-manufacturer-investigation/ index.html.

> Missouri Senator Claire McCaskill has launched an investigation into some of the country's leading prescription drug manufacturers, demanding documents and records dating back the past five years which indicate just what the companies knew of the drugs' risk for abuse as well as documents detailing marketing practices and sales presentations. Her office has sent letters to the heads of Purdue, Janssen/Johnson & Johnson, Insys, Mylan, and Depomed.

The above-referenced companies were reportedly targeted based on their role in manufacturing some of the opioid painkillers with the highest sales in 2015.

188. On September 6, 2017, Senator McCaskill's report, "Fueling an Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior Authorization" was published. The report finds that Insys manipulated the prior authorization process by misleading pharmacy benefit managers about the role of Insys in the prior authorization process and the presence of breakthrough cancer pain in potential Subsys patients.[75]

189. On September 12, 2017, Senator McCaskill convened a Roundtable Discussion on Opioid Marketing. During the hearing, Senator McCaskill stated:

> The opioid epidemic is the direct result of a calculated marketing and sales strategy developed in the 90's, which delivered three simple messages to physicians. First, that chronic pain was severely undertreated in the United States. Second, that opioids were the best tool to address that pain. And third, that opioids could treat pain without risk of serious addiction. As it turns out, these messages were exaggerations at best and outright lies at worst.
>
> * * *
>
> Our national opioid epidemic is complex, but one explanation for this crisis is simple, pure greed.

190. Professor Adriane Fugh-Berman ("Fugh-Berman"), Associate Professor at Georgetown University Medical Center and director of a program at Georgetown called Pharmed

[75] HSGAC Minority Staff Report, Insys Therapeutics and the Systemic Manipulation of Prior Authorization (2017).

Out, which conducts research on and educates the public about inappropriate pharmaceutical company marketing, also testified during the hearing. She, too, placed the blame for the opioid crisis squarely at the feet of pharmaceutical companies:

> Since the 1990's, pharmaceutical companies have stealthily distorted the perceptions of consumers and healthcare providers about pain and opioids. Opioid manufacturers use drug representatives, physicians, consumer groups, medical groups, accreditation and licensing bodies, legislators, medical boards and the federal government to advance marketing goals to sell more opioids. This aggressive marketing pushes resulted in hundreds of thousands of deaths from the overprescribing of opioids. The U.S. is about – comprises about five percent of the world population, but we use about two-thirds of the world supply of opioids.

191. Fugh-Berman also answered why doctors were able to be convinced by pharmaceutical companies' marketing efforts:

> Why the physicians fall for this? Well, physicians are overworked, overwhelmed, buried in paperwork and they feel unappreciated. Drug representatives are cheerful. They're charming. They provide both appreciation and information. Unfortunately, the information they provide is innately unreliable.
>
> Pharmaceutical companies influence healthcare providers' attitudes and their therapeutic choices through financial incentives that include research grants, educational grants, consulting fees, speaking fees, gifts and meals.

192. Fugh-Berman further described the false information provided by pharmaceutical companies and the industry creation of front organizations, including the APF, to pass industry-influenced regulations and policies:

> Pharmaceutical companies convinced healthcare providers that they were opiophobic and that they were causing suffering to their patients by denying opioids to patients with back pain or arthritis. They persuaded prescribers that patients with pain were somehow immune to addiction. Even when addiction was suspected, physicians were taught that it might not really be addiction, it might be pseudo-addiction, an invented (ph) condition that's treated by increasing opioid dosages.
>
> Industry created the American Pain Foundation co-opted other groups including medical organizations, and they change state laws to eliminate curbs on opioid prescribing. Between 2006 and 2015, pharmaceutical companies and the advocacy groups they control employ 1,350 lobbyists a year in legislative hubs. Industry-influenced regulations and policies ensure that hospitalized patients were and are

> berated paraded constantly about their level of pain and overmedicated with opioids for that pain. Even a week of opioids can lead a patient into addiction so many patients are discharged from hospitals already dependent on opioids.

193. In addition, Fugh-Berman pointed out that promotion of opioids remains ongoing despite increasing public concern about their use:

> Promotion of opioids is not in the past. Between 2013 and 2015, one in 12 physicians took out money from opioid manufacturers, a total of more than $46 million. Industry-friendly messages that pharmaceutical companies are currently perpetuating reassure physicians that prescribing opioids is safe as long as patients do not have a history of substance abuse or mental illness.

194. Fugh-Berman concluded by stating: "It is a misperception to think that most opioid deaths are caused by misuse of opioids or overdoses. In fact, many deaths occur when people are using opioids in exactly the way they were prescribed. Misuse isn't the problem; use is the problem."

3. Defendants' Marketing and Sales Strategy Worked, Resulting in Devastation.

195. The United States, including specifically Sussex County, is experiencing an unprecedented opioid addiction and overdose epidemic, costing millions in treatment, services and public safety as well as lost productivity in the workforce, economic opportunity and tax revenue.

196. By 2002, "[l]ifetime ***nonmedical*** use of OxyContin increased from 1.9 million to 3.1 million people between 2002 and 2004, and in 2004 there were 615,000 new nonmedical users of OxyContin."[76]

[76] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am. J. Pub. Health 221-27 (Feb. 2009), https:// www.ncbi.nlm.nih.gov/pmc/articles/ PMC2622774/ (hereinafter "Van Zee, *Promotion and Marketing*").

197. The carnage wrought by the Manufacturer Defendants' illegal scheme has been profound. The drug companies profited enormously as more and more people became addicted to opioids and died of overdoses.

198. For Purdue, sales grew from $48 million per year in 1996, to over $1 billion per year in 2000, to $3.1 billion per year ten years later. In 2011, pharmaceutical companies generated revenues of $11 billion from opioid sales alone.

199. By 2004, OxyContin had "become a leading drug of abuse in the United States."[77] The severity of the problem was first felt in states including Maine, West Virginia, eastern Kentucky, southwestern Virginia and Alabama, where, from 1998 through 2000, hydrocodone and oxycodone were being prescribed 2.5-5 times more often than the national average. By 2000, these same areas had a prescription rate up to 5-6 times higher than the national average. These areas were also the first to suffer increased abuse and diversion, which became apparent by 1999 and 2000. Manufacturers then expanded the geographic market by investing hundreds of millions of dollars in marketing, and the once-regional problem began to spread nationally.

200. As OxyContin sales grew between 1999 and 2002, so did sales of other opioids, including fentanyl (226%), morphine (73%) and oxycodone (402%). And, as prescriptions surged between 1999 and 2010, so did deaths from opioid overdoses (from about 4,000 to almost 17,000).[78]

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[77] Id.

[78] Gounder, *Who Is Responsible*, *supra* n.35.

201. In 2012 alone, an estimated 259 million opioid prescriptions were filled, enough to medicate every adult in the United States for a month on a round-the-clock basis.[79]

202. The escalating number of opioid prescriptions written by doctors deceived by Defendants' fraudulent and deceptive marketing scheme is the cause of a similarly dramatic increase in opioid addiction, overdose and death throughout the U.S. In August of 2016, the then-U.S. Surgeon General Vivek Murphy wrote an open letter to physicians nationwide, asking for their help combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."

203. Evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

204. Contrary to Defendants' misrepresentations, most opioid addiction begins with legitimately prescribed opioids, and therefore could have been prevented had Defendants' representations to prescribers been truthful. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet.[80]

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[79] *Opioid Painkiller Prescribing*, Centers for Disease Control and Prevention: Vital Signs (July 2014), https://www.cdc.gov/vitalsigns/opioid-prescribing/.

[80] *See* U.S. Dep't of Health & Human Servs., *2011 National Survey on Drug Use and Health* (Sept. 2012).

Numerous doctors and substance abuse counselors note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic.

205. Furthermore, "[a]ccording to the American Society of Addiction Medicine, four out of five people who try heroin today started with prescription painkillers."[81]

206. The use of prescription painkillers cost health insurers up to $72.5 billion annually in direct healthcare costs.[82]

207. Public health officials have called the current epidemic the worst drug crisis in American history.[83]

208. The County is one of the hardest hit cities in New Jersey, with significant numbers of fatal overdoses.

209. The County has administered Narcan to overdose victims with regularity, which occurrences have increased since 2014.

210. The County has responded to numerous overdoses, and expended thousands of man hours responding to services related to the related calls for services.

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[81] Keefe, *Empire of Pain*, *supra* n.3.

[82] Katherine Eban, *OxyContin: Purdue Pharma's painful medicine*, Fortune Magazine (Nov. 9, 2011), http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/ (hereinafter "Eban, *Painful Medicine*").

[83] Julie Borman, *Inside a Killer Drug Epidemic: A Look at America's Opioid Crisis*, N.Y. Times (Jan. 6, 2017), https://www.nytimes.com/2017/01/06/us/opioid-crisis-epidemic.html.

211. In 2015, opioids killed at least 918 people across the State. More alarming is that its chemical cousin, the ultra-potent fentanyl, was implicated in more than 400 deaths after being responsible for just 46 two years before.[84]

212. Data released by the Centers for Disease Control and Prevention demonstrates that the rate at which heroin and fentanyl are killing in the State far outpaces the national average.[85]

213. The County is compelled to divert significant resources each year to provide a wide range of opioid- and addiction-related services for its residents and visitors – money that it would not have had to spend but for the extreme and continuing public nuisance caused by defendants' actions – including, for instance, law enforcement and emergency response services and treatment.

214. The County continues to suffer significant financial consequences as a result of opioid over-prescription and addiction, including, but not limited to, increased law enforcement expenditures, increased public works expenditures, increased emergency and treatment services, and lost productivity, economic opportunity, and property and tax revenue. In order to properly address this unprecedented epidemic and protect the safety and welfare of its residents, the County has had to significantly modify its emergency response plan, requiring the hiring of additional permanent emergency response personnel, overtime pay, and the purchase and maintenance of additional emergency vehicles and supplies, such as Narcan –

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[84] http://www.nj.com/news/index.ssf/2016/12/nj_heroin_death_rate_was_25_times_the_skyrocketing_us_rate_in_2015.html (last visited February 20, 2018).

[85] Id.

none of which would have otherwise been necessary. Additionally, the County must now pay for and provide mental health services to its employees, who are on the front lines of assisting residents and visitors, and otherwise re-allocate County funds to cope with the Opioid epidemic.

D. Each Manufacturer Defendant Engaged in Fraudulent And Deceptive Acts that Targeted Prescribers in the County

1. Purdue

215. Purdue Pharma Inc. is a Delaware corporation with its principal place of business in Stamford, Connecticut, and The Purdue Frederick Company, Inc. is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue"). Purdue is privately held by the Sackler family – one of America's wealthiest families with a collective net worth of thirteen billion dollars. Purdue markets, sells, and distributes opioids in the County, including the following:

OxyContin (oxycodone hydrochloride extended release)	Opioid agonist[86] indicated for pain severe enough to require daily, around-the-clock, long-term opioid treatment; not indicated as an as-needed (p.r.n.) analgesic. It was first approved by the FDA in December 1995.
MS Contin (morphine sulfate extended release)	Opioid agonist; controlled-release tablet form of morphine sulfate indicated for the management of severe pain; not intended for use as a p.r.n. analgesic; first approved in May 1987 as the first formulation of an opioid pain medicine that allowed dosing every 12 hours.
Dilaudid (hydromorphone hydrochloride)	Opioid analgesic; injectable and oral formulation; eight times more potent than morphine.[87]

[86] An "agonist" medication is one that binds to and fully activates targeted receptors in the brain. They activate these neurotransmitter receptors to illicit a certain response. An "antagonist" medication, on the other hand, works to prevent the binding of other chemicals to neurotransmitters in order to block a certain response. Both may be used to offer pain relief. *Health Q&A*, Reference*, https://www.reference.com/health/difference-between-agonist-antagonist-drugs-838e9e0994a788eb (last visited February 20, 2018).

[87] *Dilaudid Addiction*, Suboxone California, https://www.suboxonecalifornia.com/suboxone-treatment/dilaudid-addiction/ (last visited February 20, 2018).

Dilaudid-HP (hydromorphone hydrochloride)	Opioid analgesic; injectable and oral high-potency and highly concentrated formulation indicated for relief of moderate-to-severe pain in opioid-tolerant patients.
Hysingla ER (hydrocodone bitrate)	Brand-name extended-release form of hydrocodone bitrate that is indicated for the management of severe pain.
Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride)	Brand-name extended-release opioid analgesic made of a combination of oxycodone hydrochloride and naloxone hydrochloride. It was approved by the FDA on July 23, 2013.

a. Purdue Falsely Marketed Low Addiction Risk to Wide Swaths of Physicians

216. In In addition to pushing OxyContin as safe and non-addictive, Purdue also promoted prescription opioids for use in non-cancer patients, who make up 86% of the total opioid market today.

217. Rather than targeting merely those physicians treating acute severe short-term (like post-operative) pain or oncologists treating end-stage cancer pain, Purdue heavily promoted OxyContin nationwide to other doctors such as general practitioners, who had little training in the treatment of serious pain or in recognizing signs of drug abuse in patients.[88] According to a report in *The New Yorke*r regarding Purdue's strategies, "[a] major thrust of the sales campaign was that OxyContin should be prescribed not merely for the kind of severe short-term pain associated with surgery or cancer but also for less acute, longer-lasting pain: arthritis, back pain, sports injuries, fibromyalgia" and "[t]he number of conditions that OxyContin could treat seemed almost unlimited."[89]

[88] Meier, *Guilty Plea*, *supra* n.22.

[89] Keefe, *Empire of Pain*, *supra* n.3.

218. Sales representatives even provided physicians with coupons redeemable for a seven- to thirty-day supply of free OxyContin, a Schedule II narcotic that by definition cannot be prescribed for more than one month at a time, with the promise that OxyContin was a safe opioid. Purdue "trained its sales representatives to carry the message that the risk of addiction was 'less than one percent,'" and "[a] consistent feature in the promotion and marketing of OxyContin was a systematic effort to minimize the risk of addiction in the use of opioids for the treatment of chronic non-cancer-related pain."[90]

219. Sales representatives marketed OxyContin as a product "'to start with and to stay with'," and Purdue deliberately exploited a misconception it knew many doctors held that oxycodone was less potent than morphine. [91] They also received training in overcoming doctors' concerns about addiction with talking points they knew to be untrue about the drug's abuse potential. *The New Yorker* reported that "[i]n 2002, a sales manager from the company, William Gergely, told a state investigator in Florida that Purdue executives 'told us to say things like it is "virtually" non-addicting.'"[92]

220. Further, "[a]ccording to training materials, Purdue instructed sales representatives to assure doctors—repeatedly and without evidence—that "'fewer than one per cent'" of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)"[93]

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[90] Van Zee, *Promotion and Marketing*, *supra* n.23.

[91] Keefe, *Empire of Pain*, *supra* n.3.

[92] *Id.*

[93] *Id.*

221. As late as 2015, if not more recently, Purdue sales representatives were telling physicians OxyContin was "addiction resistant" and had "abuse-deterrent technology."

222. And the marketing worked. Keith Humphreys, professor of psychiatry at Stanford and drug-policy adviser to the Obama Administration, said

> That's the real Greek tragedy of this—that so many well-meaning doctors got co-opted. The level of influence is just mind-boggling. Purdue gave money to continuing medical education, to state medical boards, to faux grassroots organizations.[94]

223. Additionally, Purdue tracked physicians' prescribing practices by reviewing pharmacy prescription data. Rather than reporting highly suspicious prescribing practices, Purdue used the data as part of its marketing scheme -- to track physicians who prescribed some opioids and who could be persuaded to prescribe more. Purdue also identified physicians writing large numbers of prescriptions, and particularly for high-dose 80 mg pills – potential signs of diversion and drug dealing.[95] It called those high-prescribing doctors "whales."[96]

224. Worse yet, as early as 1993 and through to the present, Purdue, including Richard Sackler and other Purdue employees, have sought and received patents to lessen the probability of addiction to the active ingredient in OxyContin and other opioids, and thus, recognize the serious risk of addiction. Yet, during the same period, Purdue, on its own and through Front Groups and

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[94] *Id.*

[95] An 80 mg tablet is equivalent in strength to 16 Vicodin tablets, and was generally reserved by doctors for patients with severe, chronic pain who had built up a tolerance over months or years. In the illegal drug trade, however, "80s" were the most in demand. For those attempting to detect how OxyContin was getting onto the black market, a physician writing a high volume of 80s was a red flag. Harriet Ryan, *et al.*, *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, L.A. Times (July 10, 2016), http://www.latimes.com/ projects/la-me-oxycontin-part2/ (hereinafter "Ryan, *More than 1 million*").

[96] Keefe, *Empire of Pain*, *supra* n. 3.

KOLs, simultaneously spent substantial sums on promotional activities and materials that falsely deny or downplay the serious risk of addiction and even promoting the concept that OxyContin is non-addictive.

225. Purdue knew about many suspicious doctors and pharmacies from prescribing records, pharmacy orders, field reports from sales representatives and, in some instances, its own surveillance operations.[97] Since 2002, Purdue maintained a confidential roster of suspected reckless prescribers known as "Region Zero." By 2013, there were more than 1,800 doctors in Region Zero, but Purdue reported only 8% of them. The *Los Angeles Times* reported that "[a] former Purdue executive, who monitored pharmacies for criminal activity, acknowledged that even when the company had evidence pharmacies were colluding with drug dealers, it did not stop supplying distributors selling to those stores."[98] Instead, Purdue supplied prescription opioids to these stores, prioritized its own profits (and the bank accounts of its owners) ahead of public safety, and downplayed the risk of addiction.

b. Purdue Funded Publications and Presentations with False and Misleading Messaging

226. As explained above, Purdue's false marketing scheme did not end with its own sales representatives and branded marketing materials. It extended far beyond, engaging third parties

[97] Purdue's "Abuse and Diversion Detection" program requires its sales representatives to report to the company any facts that suggest a healthcare provider to whom it markets opioids may be involved in the abuse or illegal diversion of opioid products. When a provider is reported under the program, Purdue purportedly conducts an internal inquiry regarding the provider to determine whether he or she should be placed on a "no-call" list. If a provider is placed on this list, Purdue sales representatives may no longer contact the provider to promote the company's opioid products. Bill Fallon, *Purdue Pharma agrees to restrict marketing of opioids*, Stamford Advocate (Aug. 25, 2015, 3:32 PM), http://www.stamfordadvocate.com/business/article/Purdue-Pharma-agrees-to-restrict-marketing-of-6464800.php (hereinafter "Fallon, *Purdue Pharma agrees*").

[98] Ryan, *More than 1 Million*, *supra* n. 92.

including doctors and front groups to spread the false message of prescription opioids' safety and efficacy.

227. One extension of Purdue's marketing scheme was its plan to cause the publication and distribution of false and deceptive guidelines on opioid prescribing. For example, as set forth above, Purdue paid $100,000 to the FSMB to help print and distribute its guidelines on the use of opioids to treat chronic pain to ***700,000*** practicing doctors.

228. One of the advisors for FSMB 2007 publication "Responsible Opioid Prescribing: A Physician's Guide" and its 2012 update was Haddox, a longtime member of Purdue's speakers' bureau who became a Purdue vice president.

229. Similarly,[99] multiple videos feature Fine delivering educational talks about the drugs. In one video from 2011 titled "Optimizing Opioid Therapy," he sets forth a "Guideline for Chronic Opioid Therapy" discussing "opioid rotation" (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it may take four or five switches over a person's "lifetime" to manage pain.[100] He states the "goal is to improve effectiveness which is different from efficacy and safety." Rather, for chronic pain patients, effectiveness "is a balance of therapeutic good and adverse events ***over the course of years***." The entire program teaches that opioids are appropriate treatment over a "protracted period of time" and even over a patient's entire "lifetime." He even suggests that opioids can be used to treat ***sleep apnea***. He further states that

[99] Weber, *Two Leaders in Pain*, *supra* n.69.

[100] Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.

the associated risks of addiction and abuse can be managed by doctors and evaluated with "tools," but leaves that for "a whole other lecture."[101]

230. Purdue provided many "teaching" materials free of charge to the Joint Commission.

231. Purdue also deceptively marketed the use of opioids for chronic pain through the APF, which was shut down after the launching of the Senate investigation in 2012. In 2010 alone, the APF received 90% of its funding from drug and medical device companies, including from Purdue. Purdue paid APF unspecified amounts in 2008 and 2009 and between $100,000 and $499,999 in 2010.[102]

c. The Guilty Pleas

232. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay $600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science. Additionally, Michael Friedman ("Friedman"), the company's president, pled guilty to a misbranding charge and agreed to pay $19 million in fines; Howard R. Udell ("Udell"), Purdue's top lawyer, also pled guilty and agreed to pay $8 million in fines; and Paul D. Goldenheim ("Goldenheim"), its former medical director, pled guilty as well and agreed to pay $7.5 million in fines.

233. In a statement announcing the guilty plea, John Brownlee ("Brownlee"), the U.S. Attorney for the Western District of Virginia, stated:

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[101] *Id.*

[102] American Pain Foundation Partner Report, GuideStar, http://www.guidestar.org/PartnerReport.aspx?ein=52-2002328&Partner=Demo (last visited February 20, 2018).

Purdue claimed it had created the miracle drug – a low risk drug that could provide long acting pain relief but was less addictive and less subject to abuse. ***Purdue's marketing campaign worked, and sales for OxyContin skyrocketed – making billions for Purdue and millions for its top executives.***

But OxyContin offered no miracles to those suffering in pain. Purdue's claims that OxyContin was less addictive and less subject to abuse and diversion were false – and Purdue knew its claims were false. The result of their misrepresentations and crimes sparked one of our nation's greatest prescription drug failures. . . . OxyContin was the child of marketeers and bottom line financial decision making.[103]

234. Brownlee characterized Purdue's criminal activity as follows:

First, ***Purdue trained its sales representatives to falsely inform health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse***. Purdue ordered this training even though its own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet by simply crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe.

Second, ***Purdue falsely instructed its sales representatives to inform health care providers that OxyContin could create fewer chances for addiction*** than immediate-release opioids.

Third, ***Purdue sponsored training that falsely taught Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse*** than short-acting opioids.

Fourth, ***Purdue falsely told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance*** to the drug.

And fifth, ***Purdue falsely told health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids***, and could be used to "weed out" addicts and drug seekers.[104]

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[103] Testimony of The Hon. John L. Brownlee, U.S. Attorney for the Western District of Virginia, (July 31, 2007), https://www.judiciary.senate.gov/imo/media/doc/Brownlee%20Testimony%20073107.pdf

[104] *Id*.

235. Specifically, Purdue pled guilty to illegally misbranding OxyContin in an effort to mislead and defraud physicians and consumers, while Friedman, Udell and Goldenheim pled guilty to the misdemeanor charge of misbranding OxyContin, for introducing misbranded drugs into interstate commerce in violation of 21 U.S.C. §§331(a), 333(a)(1)-(2) and 352(a).

236. The guilty plea and fine did not dissuade Purdue or its executives. After the settlement, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and to fund seemingly neutral organizations to disseminate the message that opioids were effective and non-addictive. Purdue continues to aggressively market the liberal prescribing of opioids for chronic pain while diminishing the associated dangers of addiction.

237. After Purdue entered its guilty plea in 2007, "it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly **nine hundred million dollars** on lobbying and political contributions—eight times what the gun lobby spent during that period."[105] (emphasis added).

238. Purdue has earned more than $31 billion from OxyContin, the nation's bestselling painkiller, which constitutes approximately 30% of the United States market for painkillers. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up threefold from 2006 sales of $800 million.[106]

[105] Keefe, *Empire of Pain*, *supra* n.3.

[106] Eban, *Painful Medicine*, *supra* n.78.

239. Purdue also made thousands of payments to physicians nationwide, including to physicians in the County, for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services.

2. Janssen

240. Janssen markets, sells, and distributes the following opioids in the County:

Duragesic (fentanyl)	Opioid analgesic delivered via skin patch; contains gel form of fentanyl, a synthetic opioid that is up to 100 times more potent than morphine; delivers fentanyl at regulated rate for up to 72 hours; first approved by the FDA in August 1990.
Nucynta ER (tapentadol hydrochloride)	Opioid agonist; extended-release formulation indicated for severe pain.
Nucynta (tapentadol hydrochloride)	Immediate-release version of tapentadol hydrochloride for the management of moderate to severe acute pain.

241. Janssen introduced Duragesic in 1990. It is indicated for the "management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Janssen also markets Nucynta, which was first approved by the FDA in 2008, formulated in tablet form and in an oral solution and indicated for the "relief of moderate to severe acute pain in patients 18 years of age or older." Additionally, Janssen markets Nucynta ER, which was first approved by the FDA in 2011 in tablet form. Initially, it was indicated for the "management of . . . pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." This pain indication was later altered to "management of moderate to severe chronic pain in adults" and "neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults." Janssen sold Nucynta and Nucynta ER to Depomed in 2015 for $1.05 billion.

a. The FDA Warned Janssen Regarding Its False Messaging

242. On February 15, 2000, the FDA sent Janssen a letter concerning the alleged dissemination of "homemade" promotional pieces that promoted Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA explained that the "homemade" promotional pieces were "false or misleading because they contain misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance."

243. The March 30, 2000 letter identified specific violations, including misrepresentations that Duragesic had a low potential for abuse:

- You present the claim, "Low abuse potential!" This claim suggests that Duragesic has less potential for abuse than other currently available opioids. However, this claim has not been demonstrated by substantial evidence. Furthermore, this claim is contradictory to information in the approved product labeling (PI) that states, "Fentanyl is a Schedule II controlled substance and can produce drug dependence similar to that produced by morphine." Therefore, this claim is false or misleading.[107]

244. The March 30, 2000 letter also stated that the promotional materials represented that Duragesic was "more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence." Specifically, the FDA stated that Janssen was marketing Duragesic for indications beyond the treatment of chronic pain that cannot otherwise be managed, for which it was approved:

- You present the claim, "It's not just for end stage cancer anymore!" This claim suggests that Duragesic can be used for any type of pain management. However, the PI for Duragesic states, "Duragesic (fentanyl transdermal system) is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by

[107] NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutica (Mar. 30, 2000) at 2.

> lesser means . . . ." Therefore, the suggestion that Duragesic can be used for any type of pain management promotes Duragesic[] for a much broader use than is recommended in the PI, and thus, is misleading. In addition, the suggestion that Duragesic can be used to treat any kind of pain is contradictory to the boxed warning in the PI. Specifically, the PI states,
>
> - BECAUSE SERIOUS OR LIFE-THREATENING HYPOVENTILATION COULD OCCUR, DURAGESIC® (FENTANYL TRANSDERMAL SYSTEM) IS CONTRAINDICATED:
>
> - In the management of acute or post-operative pain, including use in out-patient surgeries . . . .[108]

245. The March 30, 2000 letter also stated Janssen failed to adequately present "contraindications, warnings, precautions, and side effects with a prominence and readability reasonably comparable to the presentation of information relating to the effectiveness of the product":

> Although this piece contains numerous claims for the efficacy and safety of Duragesic, ***you have not presented any risk information*** concerning the boxed warnings, contraindications, warnings, precautions, or side effects associated with Duragesic's use . . . . Therefore, this promotional piece is lacking in fair balance, or otherwise misleading, because it fails to address important risks and restrictions associated with Duragesic therapy.[109]

246. On September 2, 2004, the U.S. Department of Health and Human Services ("HHS") also sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic," including, specifically, "suggesting that Duragesic has a lower potential for abuse compared to other opioid products."

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[108] *Id*. at 2-3.

[109] *Id*. at 3 (emphasis in original).

247. The September 2, 2004 letter warned Janssen regarding its claims that Duragesic had a low reported rate of mentions in the Drug Abuse Warning Network ("DAWN") as compared to other opioids. The letter stated that the claim was false or misleading because the claim was not based on substantial data and because the lower rate of mentions was likely attributable to Duragesic's lower frequency of use compared to other opioids listed in DAWN:

> The file card presents the prominent claim, "Low reported rate of mentions in DAWN data," along with Drug Abuse Warning Network (DAWN) data comparing the number of mentions for Fentanyl/combinations (710 mentions) to other listed opioid products, including Hydrocodone/combinations (21,567 mentions), Oxycodone/combinations (18,409 mentions), and Methadone (10,725 mentions). The file card thus suggests that Duragesic is less abused than other opioid drugs.
>
> This is false or misleading for two reasons. First, we are not aware of substantial evidence or substantial clinical experience to support this comparative claim. The DAWN data cannot provide the basis for a valid comparison among these products. As you know, DAWN is not a clinical trial database. Instead, it is a national public health surveillance system that monitors drug-related emergency department visits and deaths. If you have other data demonstrating that Duragesic is less abused, please submit them.
>
> Second, Duragesic is not as widely prescribed as other opioid products. As a result, the relatively lower number of mentions could be attributed to the lower frequency of use, and not to a lower incidence of abuse. The file card fails to disclose this information.[110]

248. The September 2, 2004 letter also details a series of unsubstantiated, false or misleading claims regarding Duragesic's effectiveness. The letter concluded that various claims made by Janssen were insufficiently supported, including that:

- "'Demonstrated effectiveness in chronic back pain with additional patient benefits, . . . 86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep.'"

[110] Warning Letter from Thomas W. Abrams, U.S. Department of Health and Human Services, to Ajit Shetty, Janssen Pharmaceutical, Inc. (Sept. 2, 2004), https://www.pharmamedtechbi.com/~/media/Images/Publications/Archive/The%20Pink%20Sheet/66/038/00660380018/040920_ duragesic_letter.pdf at 2.

- "'All patients who experienced overall benefit from DURAGESIC would recommend it to others with chronic low back pain.'"
- "'Significantly reduced nighttime awakenings.'"
- "'Significant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index.'"
- "'Significant improvement in physical functioning summary score.'"
- "'Significant improvement in social functioning.'"[111]

249. In addition, the September 2, 2004 letter identifies "outcome claims [that] are misleading because they imply that patients will experience improved social or physical functioning or improved work productivity when using Duragesic." The claims include "'1,360 loaves . . . and counting,' '[w]ork, uninterrupted,' '[l]ife, uninterrupted,' '[g]ame, uninterrupted,' '[c]hronic pain relief that supports functionality,' '[h]elps patients think less about their pain,' and '[i]mprove[s] . . . physical and social functioning.'" The September 2, 2004 letter states: "Janssen has not provided references to support these outcome claims. We are not aware of substantial evidence or substantial clinical experience to support these claims."[112]

250. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been "'examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch'" and noted the possibility "that patients and physicians might be unaware of the risks" of using the

[111] *Id*. at 2-3.

[112] *Id*. at 3.

fentanyl transdermal patch, which is a potent opioid analgesic meant to treat chronic pain that does not respond to other painkillers.

b. Janssen Funded False Publications and Presentations

251. Despite these repeated warnings, Janssen continued to falsely market the risks of opioids. For example, in 2009, PriCara, a "Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.," sponsored a 2009 brochure directed toward patients, "Finding Relief: Pain Management for Older Adults." The brochure included a free DVD featuring actress Kathy Baker, who played a doctor in the popular television series "Picket Fences."

252. The brochure represented that it was a source for older adults to gain accurate information about treatment options for effective pain relief:

> This program is aimed specifically at older adults and what they need to know to get effective pain relief. You will learn that there are many pathways to this relief.
>
> You will learn about your options for pain management and how to find the treatment that's right for you. By learning more about pain and the many ways it can be treated, you are taking solid steps toward reducing the pain you or a loved one may be feeling.[113]

253. Despite representing itself as a source of accurate information, the brochure included false and misleading information about opioids, including a section seeking to dispel purported "myths" about opioid usage:

> **Opioid Myths**
>
> **Myth:** Opioid medications are always addictive.
>
> **Fact:** Many studies show that opioids are ***rarely*** addictive when used properly for the management of chronic pain.

[113] *Finding Relief, Pain Management for Older Adults* (2009).

> **Myth:** Opioids make it harder to function normally.
>
> **Fact:** When used correctly for appropriate conditions, opioids may make it ***easier*** for people to live normally.
>
> **Myth:** Opioid doses have to get bigger over time because the body gets used to them.
>
> **Fact:** Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.[114]

254. Among the "Partners" listed in "Finding Relief: Pain Management for Older Adults" are the AAPM, the American Geriatrics Society ("AGS") and the AGS Foundation for Health in Aging. Janssen (along with Purdue and Endo) funded AAPM. The AGS and the AGS Foundation for Health in Aging published a pain guide titled "Finding Relief: Pain Management for Older Adults," which was funded by Janssen.[115]

255. In addition, Janssen disseminated false information about opioids on the website Prescribe Responsibly, which remains publicly accessible at www.prescriberesponsibly.com. According to the website's legal notice, all content on the site "is owned or controlled by Janssen."[116] The website includes numerous false or misleading representations concerning the relative safety of opioids and omissions of the risks associated with taking them. For example, it states that while practitioners are often concerned about prescribing opioids due to "questions of addiction," such concerns "are often overestimated. According to clinical opinion polls, true

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[114] *Id*. (emphasis in original).

[115] *Id*.

[116] *Legal Notice*, Prescribe Responsibly, https://www.prescriberesponsibly.com/legal-notice (last visited February 20, 2018).

addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesic[] . . . therapy."[117]

256. Prescribe Responsibly also compared the risks of opioid use favorably to those associated with non-steroidal anti-inflammatory drugs ("NSAIDs"), such as aspirin and ibuprofen, and stated that many patients develop tolerance for opioid side effects:

> Opioid analgesics are often the first line of treatment for many painful conditions and may offer advantages over nonsteroidal anti-inflammatory drugs (NSAIDs). Opioid analgesics, for example, have no true 'ceiling dose' for analgesia and do not cause direct organ damage; however, they do have several possible side effects, including constipation, nausea, vomiting, a decrease in sexual interest, drowsiness, and respiratory depression. With the exception of constipation, many patients often develop tolerance to most of the opioid analgesic-related side effects.[118]

257. Further, Prescribe Responsibly repeats the scientifically unsupported discussion of "pseudoaddiction" as "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately, the inappropriate behavior ceases."[119] Thus, pseudoaddiction is defined as a condition requiring the prescription of more or stronger opioids.

258. Janssen also made thousands of payments to physicians nationwide, including to County physicians, for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services.

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[117] *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/opioid-pain-management (last visited February 20, 2018).

[118] *Id.*

[119] *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/before-prescribing-opioids (last visited February 20, 2018).

259. As people became more and more hooked on prescription pain killers, they moved to heroin, and increasingly to fentanyl, which is even more potent and cheaper than heroin, and which as set forth above was being deceptively marketed by Janssen, causing a rise in heroin and fentanyl overdose deaths.

3. Endo

260. Endo markets, sells, and distributes the following opioids in the County:

Opana ER (oxymorphone hydrochloride)	Opioid agonist; extended-release tablet formulation; first drug in which oxymorphone is available in an oral, extended-release formulation; first approved in 2006.
Opana (oxymorphone hydrochloride)	Opioid agonist; first approved in 2006.
Percodan (oxymorphone hydrochloride and aspirin)	Branded tablet combining oxymorphone hydrochloride and aspirin; first approved in 1950; first marketed by Endo in 2004.
Percocet (oxymorphone hydrochloride and acetaminophen)	Branded tablet that combines oxymorphone hydrochloride and acetaminophen; first approved in 1999; first marketed by Endo in 2006.
Oxycodone	Generic product.
Oxymorphone	Generic product.
Hydromorphone	Generic product.
Hydrocodone	Generic product.

261. The FDA approved an injectable form of Opana in 1959 (then known as Numorphan) which was indicated "for the relief of moderate to severe pain" and "for preoperative medication, for support of anesthesia, for obstetrical analgesia, and for relief of anxiety in patients with dyspnea associated with pulmonary edema secondary to acute left ventricular dysfunction."

However, oxymorphone drugs—which included Numorphan—were removed from the market in the 1970s due to widespread abuse.[120]

262. In 2006, the FDA approved a tablet form of Opana in 5 mg and 10 mg dosage strengths. The tablet form was "indicated for the relief of moderate to severe acute pain where the use of an opioid is appropriate." Also in 2006, the FDA approved Opana ER, an extended-release tablet version of Opana available in 5 mg, 10 mg, 20 mg and 40 mg tablet dosage strengths. Opana ER was indicated "for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time." Endo's goal was to use Opana ER to take market share away from OxyContin; thus it was marketed as being safer, with less abuse potential than OxyContin because of its crush-resistance.

263. According to Endo's annual reports, sales of Opana and Opana ER regularly generate several hundred million dollars in annual revenue for the company, growing from $107 million in 2007 to as high as $384 million in 2011. Over the last ten years, Percocet has generated an average of well over $100 million in annual revenue for the company.

a. Endo Falsely Marketed Opana ER as Crush Resistant

264. In December 2011, the FDA approved a reformulated version of Opana ER, which Endo claimed offered "safety advantages" over the original formulation because the latter "'is resistant to crushing by common methods and tools employed by abusers of prescription opioids . . . [and] is less likely to be chewed or crushed even in situations where there is no intent for abuse, such as where patients inadvertently chew the tablets, or where caregivers attempt to crush the

[120] John Fauber & Kristina Fiore, *Opana Gets FDA Approval Despite History of Abuse, Limited Effectiveness in Trials*, Milwaukee Journal Sentinel (May 9, 2015), http://archive.jsonline.com/watchdog/watchdogreports/opana-gets-fda-approval-despite-history-of-abuse-limited-effectiveness-in-trials-b99494132z1-303198321.html/.

tablets for easier administration with food or by gastric tubes, or where children accidentally gain access to the tablets.'"

265. Endo publicized the reformulated version of Opana ER as "crush-resistant." To combat the fear of opioids, sales representatives touted it to doctors as a safer option due to its crush-resistance and extended release. In a December 12, 2011, press release announcing FDA approval of the reformulated Opana ER, Endo's executive vice president for research and development and chief scientific officer highlighted the reformulated version's safety characteristics:

> "FDA's approval of this new formulation of Opana ER is an important milestone for both the Long Acting Opioid category as well as Endo's branded pharmaceutical portfolio. . . . Patient safety is our top concern and addressing appropriate use of opioids is a responsibility that we take very seriously. We firmly believe this new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers."

266. However, in October 2012, the CDC issued a health alert noting that 15 people in Tennessee had contracted thrombotic thrombocytopenic purpura, a rare blood-clotting disorder, after injecting reformulated Opana ER. In response, Endo's chief scientific officer stated that, while Endo was looking into the data, he was not especially concerned: "'Clearly, we are looking into this data, . . . but it's in a very, very distinct area of the country.'"[121]

267. Shortly thereafter, the FDA determined that Endo's conclusions about the purported safety advantages of the reformulated Opana ER were unfounded. In a May 10, 2013 letter to Endo, the FDA found that the tablet was still vulnerable to "'cutting, grinding, or

[121] Jake Harper & Kelly McEvers, *How A Painkiller Designed To Deter Abuse Helped Spark An HIV Outbreak*, National Public Radio (Apr. 1, 2016), http://www.npr.org/sections/health-shots/2016/04/01/472538272/how-a-painkiller-designed-to-deter-abuse-helped-spark-an-hiv-outbreak.

chewing,'" "'can be prepared for insufflation (snorting) using commonly available tools and methods,'" and "'can [be readily] prepared for injection.'" It also warned that preliminary data suggested "the troubling possibility that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation."

268. A 2014 study co-authored by an Endo medical director corroborated the FDA's warning. This 2014 study found that while overall abuse of Opana had fallen following Opana ER's reformulation, it also found that injection had become the preferred way of abusing the drug.[122] However, the study reassured that it was not possible to draw a causal link between the reformulation and injection abuse.

269. The study's failure to adequately warn healthcare providers and the public was catastrophic. On April 24, 2015, the CDC issued a health advisory concerning its investigation of "a large outbreak of recent human immunodeficiency virus (HIV) infections among persons who inject drugs."[123] The CDC specifically attributed the outbreak to the injection of Opana ER. As the advisory explained:

> From November 2014 to January 2015, ISDH identified 11 new HIV infections in a rural southeastern County where fewer than 5 infections have been identified annually in the past. As of April 21, 2015, an on-going investigation by ISDH with assistance from CDC has identified 135 persons with newly diagnosed HIV infections in a community of 4,200 people; 84% were also HCV infected. Among 112 persons interviewed thus far, 108 (96%) injected drugs; all reported dissolving and injecting tablets of the prescription-type opioid oxymorphone (OPANA® ER) using shared drug preparation and injection equipment.[124]

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[122] *Id*.

[123] *Outbreak of Recent HIV and HCV Infections Among Persons Who Inject Drugs*, Centers for Disease Control and Prevention, https://emergency.cdc.gov/ han/han00377.asp (last visited February 20, 2018).

[124] *Id*.

b. New York's Investigation Found Endo Falsely Marketed Opana ER

270. On February 18, 2017, the State of New York announced a settlement with Endo requiring it "to cease all misrepresentations regarding the properties of Opana ER [and] to describe accurately the risk of addiction to Opana ER."[125] In the Assurance of Discontinuance that effectuated the settlement, the State of New York revealed evidence showing that Endo had known about the risks arising from the reformulated Opana ER even before it received FDA approval.

271. Among other things, the investigation concluded that:

- ***Endo improperly marketed Opana ER as designed to be crush resistant, when Endo's own studies dating from 2009 and 2010 showed that the pill could be crushed and ground;***
- ***Endo improperly instructed its sales representatives to diminish and distort the risks associated with Opana ER, including the serious danger of addiction; and***
- ***Endo made unsupported claims comparing Opana ER to other opioids and failed to disclose accurate information regarding studies addressing the negative effects of Opana ER.***

272. In October 2011, Endo's director of project management e-mailed the company that had developed the formulation technology for reformulated Opana ER to say there was little or no difference between the new formulation and the earlier formulation, which Endo withdrew due to risks associated with grinding and chewing:

> "***We already demonstrated that there was little difference between [the original and new formulations of Opana] in Study 108 when both products were ground. FDA deemed that there was no difference*** and this contributed to their statement that we had not shown an incremental benefit. ***The chewing study (109) showed***

[125] Press Release, Attorney General Eric T. Schneiderman, *A.G. Schneiderman Announces Settlement With Endo Health Solutions Inc. & Endo Pharmaceuticals Inc. Over Marketing of Prescription Opioid Drugs* (Mar. 3, 2016), https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals.

> ***the same thing no real difference*** which the FDA used to claim no incremental benefit."[126]

273. Endo conducted two additional studies to test the reformulated Opana ER's crush resistance. Study 901 tested whether it was more difficult to extract reformulated Opana ER than the original version, and whether it would take longer to extract from reformulated Opana ER than from the original version. The test revealed that both formulations behaved similarly with respect to manipulation time and produced equivalent opioid yields.

274. The settlement also identified and discussed a February 2013 communication from a consultant hired by Endo to the company, in which the consultant concluded that "'[t]he initial data presented do not necessarily establish that the reformulated Opana ER is tamper resistant.'" The same consultant also reported that the distribution of the reformulated Opana ER had already led to higher levels of abuse of the drug via injection.[127]

275. Regardless, pamphlets produced by Endo and distributed to physicians misleadingly marketed the reformulated Opana ER as "'designed to be' crush resistant," and Endo's sales representative training identified Opana ER as "CR," short for crush resistant.[128]

276. The Office of the Attorney General of New York also revealed that the "managed care dossier" Endo provided to formulary committees of healthcare plans and pharmacy benefit managers misrepresented the studies that had been conducted on Opana ER. The dossier was distributed in order to assure the inclusion of reformulated Opana ER in their formularies.

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[126] *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No. 15-228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 5 (Mar. 1, 2016), https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

[127] *Id*. at 6.

[128] *Id*.

277. According to Endo's vice president for pharmacovigilance and risk management, the dossier was presented as a complete compendium of all research on the drug. However, it omitted certain studies: Study 108 (completed in 2009) and Study 109 (completed in 2010), which showed that reformulated Opana ER could be ground and chewed.

278. The settlement also detailed Endo's false and misleading representations about the non-addictiveness of opioids and Opana. Until April 2012, Endo's website for the drug, www.opana.com, contained the following representation: "'Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.'"[129] However, Endo had no basis for their representations.

279. The Office of the Attorney General of New York also disclosed that training materials provided by Endo to sales representatives stated that the "'[s]ymptoms of withdrawal do not indicate addiction.'"[130] This representation is inconsistent with the diagnosis of opioid-use disorder as provided in the Diagnostic and Statistical Manual of Mental Disorders by the American Psychiatric Association (Fifth Edition).

280. The Office of the Attorney General of New York also found that Endo trained its sales representatives to falsely distinguish addiction from "pseudoaddiction," which it defined as a condition in which patients exhibit drug-seeking behavior that resembles but is not the same as addiction. However, Endo's vice president for pharmacovigilance and risk management testified that he was not aware of any research validating the concept of pseudoaddiction.

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[129] *Id*.

[130] *Id*. at 7.

281. On June 9, 2017, the FDA asked Endo to voluntarily cease sales of Opana ER after determining that the risks associated with its abuse outweighed the benefits. According to Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, the risks include "several serious problems," including "outbreaks of HIV and Hepatitis C from sharing the drug after it was extracted by abusers" and "a[n] outbreak of serious blood disorder." If Endo does not comply with the request, Dr. Woodcock stated that the FDA would issue notice of a hearing and commence proceedings to compel its removal.

c. Endo Funded False Publications and Presentations

282. Like several of the other Manufacturer Defendants, Endo provided substantial funding to purportedly neutral medical organizations, including APF.

283. For example, in April 2007, Endo sponsored an article aimed at prescribers, written by Dr. Charles E. Argoff in *Pain Medicine News*, titled "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain."[131]

284. The article commenced with the observation that "[a]n estimated 50 to 60 million people . . . suffer from chronic pain." It continued:

> Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.[132]

[131] Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, http://www.painmedicinenews.com/download/BtoB_Opana_WM.pdf.

[132] *Id*.

285. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids. It concluded by saying that "use of opioids may be effective in the management of chronic pain."

286. Later, in 2014, Endo issued a patient brochure titled "Understanding Your Pain: Taking Oral Opioid Analgesics." It was written by nurses Margo McCaffery and Chris Pasero and edited by APF board member Portenoy.

287. The brochure included numerous false and misleading statements minimizing the dangers associated with prescription opioid use. Among other things, the brochure falsely and misleadingly represented that:

> Addiction **IS NOT** when a person develops "withdrawal" (such as abdominal cramping or sweating) after the medicine is stopped quickly or the dose is reduced by a large amount. Your doctor will avoid stopping your medication suddenly by slowly reducing the amount of opioid you take before the medicine is completely stopped. Addiction also **IS NOT** what happens when some people taking opioids need to take a higher dose after a period of time in order for it to continue to relieve their pain. This normal "tolerance" to opioid medications doesn't affect everyone who takes them and does not, by itself, imply addiction. If tolerance does occur, it does not mean you will "run out" of pain relief. Your dose can be adjusted or another medicine can be prescribed.
>
> * * *
>
> *How can I be sure I'm not addicted?*
>
> - Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problems.
> - Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons – to relieve your pain and improve your function. You are not addicted.
>
> * * *

Your doctor or nurse may instruct you to do some of the following:

- Take the next dose before the last dose wears off. If pain is present most of the day and night, the pain medicine may be taken at regularly scheduled times. If you are taking a short-acting opioid, this usually means taking it every 4 hours. You may need to set your alarm, especially at night, to be sure you take your dose before the pain returns and wakes you up.
- If your pain comes and goes, take your pain medicine when pain first begins, before it becomes severe.
- If you are taking a long-acting opioid, you may only need to take it every 8 to 12 hours, but you may also need to take a short-acting opioid in between for any increase in pain.[133]

288. In 2008, Endo also provided an "educational grant" to PainEDU.org, which produced a document titled "Screener and Opioid Assessment for Patients with Pain (SOAPP) Version 1.0-14Q." Endo and King Pharmaceuticals sponsor PainEDU.org.[134] SOAPP describes itself "as a tool for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require." It falsely highlights purportedly "recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems."

289. Endo also sponsored the now-defunct website painknowledge.com, which was created by APF and stated it was "a one-stop repository for print materials, educational resources, and physician tools across the broad spectrum of pain assessment, treatment, and management approaches."[135] Among other featured content, painknowledge.com included a flyer titled "Pain:

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[133] Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharmaceuticals (2004), http://www.thblack.com/ links/RSD/Understand_Pain_Opioid_Analgesics.pdf (emphasis in original).

[134] B. Eliot Cole, *Resources for Education on Pain and Its Management: A Practitioner's Compendium* 2 (Am. Society of Pain Educators 2009), https:// www.paineducators.org/wp-content/uploads/2012/12/ASPE-ResForEducationOnPainAn.pdf.

[135] *AboutPainKnowledge.org*, PainKnowledge, http://web.archive.org/web/ 2012011 9124921/http://www.painknowledge.org/aboutpaink.aspx (last visited February 20, 2018).

Opioid Therapy," which failed to warn of significant adverse effects that could arise from opioid use, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, decreased tolerance, dependence and addiction.

290. Endo, along with Janssen and Purdue, also provided grants to APF to distribute Exit Wounds, discussed above.[136]

291. Endo also made thousands of payments to physicians nationwide, including to County physicians, for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services.

d. The FDA Requested Endo Withdraw Opana ER Due to the Public Health Consequences of Abuse

292. On June 8, 2017, the FDA requested that Endo remove reformulated Opana ER from the market "based on its concern that the benefits of the drug may no longer outweigh its risks."[137] According to the FDA's press release, it sought removal "due to the public health consequences of abuse." The decision to seek Opana ER's removal from sale followed a March 2017 FDA advisory committee meeting, during which a group of independent experts voted 18-8 that the drug's benefits no longer outweigh the risks associated with its use. Should Endo choose not to remove Opana ER due to the FDA's request, the agency stated that it will take steps to formally require its removal by withdrawing approval.

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[136] *Iraq War Veteran Amputee, Pain Advocate and New Author Release Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families*, Coalition for Iraq + Afghanistan Veterans, https://web.archive.org/web/ 20160804131030/http://coalitionforveterans.org/2009/10/iraq-war-veteran-amputee-pain-advocate-and-new-author-releases-exit-wounds-a-survival-guide-to-pain-management-for-returning-veterans-and-their-families/ (last visited February 20, 2018).

[137] Press Release, U.S. Food & Drug Administration, F*DA Requests Removal of Opana ER for Risks Related to Abuse* (June 8, 2017), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm562401.htm.

293. Opana ER is prescribed in the County.

4. Cephalon & Teva

294. Cephalon markets, sells, and distributes the following opioids in the County:

Actiq (fentanyl citrate)	Opioid analgesic; oral transmucosal lozenge; indicated only for the management of breakthrough pain (or "BTP") in cancer patients – pain that for a short time "breaks through" medication that otherwise effectively controls a patient's persistent pain – in patients 16 and older with malignancies; commonly referred to as a lollipop because designed to look and perform like one; approved in 1998 with restricted distribution program.
Fentora (fentanyl buccal)	Rapid-release tablet for BTP in cancer patients who are already receiving and tolerant of around-the-clock opioid therapy; approved 2006.
Generic of OxyContin (oxycodone hydrochloride)	Opiate agonist.

295. Actiq is designed to resemble a lollipop and is meant to be sucked on at the onset of intense BTP in cancer patients. It delivers fentanyl citrate, a powerful opioid agonist that is 80 times stronger than morphine,[138] rapidly into a patient's bloodstream through the oral membranes.[139] Because it is absorbed through those membranes, it passes directly into circulation without having to go through the liver or stomach, thereby providing faster relief.[140]

[138] *See* John Carreyrou, *Narcotic "Lollipop" Becomes Big Seller Despite FDA Curbs*, Wall St. J. (Nov. 3, 2006), https://www.opiates.com/media/narcotic-lollipop-becomes-big-seller-despite-fda-curbs/ (hereinafter "Carreyrou, *Narcotic Lollipop*").

[139] Actiq would later become part of a category of opioids now known as transmucosal immediate-release fentanyl ("TIRF") products. "Transmucosal" refers to the means through which the opioid is delivered into a patient's bloodstream, across mucous membranes, such as inside the cheek, under the tongue or in the nose.

[140] *Cephalon, Inc.*, Company-Histories.com, http://www.company-histories.com/Cephalon-Inc-Company-History.html (last visited February 20, 2018).

296. In November 1998, the FDA approved Actiq for only a very narrow group of people – cancer patients "with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[141]

297. Understanding the risks of introducing such an intense opioid analgesic to the market, the FDA provided approval of Actiq "***ONLY*** for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[142] Further, the FDA explicitly stated that Actiq "***must not*** be used in opioid non-tolerant patients," was contraindicated for the management of acute or postoperative pain, could be deadly to children and was "intended to be used only in the care of opioid-tolerant cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain."

298. The FDA also required that Actiq be provided only in compliance with a strict risk-management program that explicitly limited the drug's direct marketing to the approved target audiences, defined as oncologists, pain specialists, their nurses and office staff.[143]

299. In October 2000, Cephalon acquired the worldwide product rights to Actiq and began marketing and selling Actiq in the United States.

300. Cephalon purchased the rights to Fentora, an even faster-acting tablet formulation of fentanyl, from Cima Labs, and submitted a new drug application to the FDA in August 2005.

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[141] 1998 FDA Label.

[142] NDA 20-747 Letter from Cynthia McCormick, Center for Drug Evaluation and Research, to Patricia J. Richards, Anesta Corporation, http://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20747ltr.pdf.

[143] Carreyrou, *Narcotic Lollipop*, *supra* n. 135.

In September 2006, Cephalon received FDA approval to sell this faster-acting version of Actiq, but once again, concerned about the power and risks inherent to fentanyl, the FDA limited Fentora's approval to the treatment of BTP in cancer patients who were already tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Cephalon began marketing and selling Fentora in October 2006.

a. Cephalon Falsely and Aggressively Marketed Cancer Drug Actiq to Non-Cancer Treating Physicians

301. Due to the FDA's restrictions, Actiq's consumer base was limited, as was its potential for growing revenue. In order to increase its revenue and market share, Cephalon needed to find a broader audience and thus began marketing its lollipop to treat headaches, back pain, sports injuries and other chronic non-cancer pain, targeting non-oncology practices, including, but not limited to, pain doctors, general practitioners, migraine clinics, anesthesiologists and sports clinics. It did so in violation of applicable regulations prohibiting the marketing of medications for off-label use and in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

302. According to "data gathered from a network of doctors by research firm ImpactRx between June 2005 and October 2006" ("ImpactRx Survey"), Cephalon sales representatives' visits to non-oncologists to pitch Actiq increased six fold between 2002 and 2005. Cephalon representatives would reportedly visit non-oncologists monthly, providing up to 60 or 70 coupons (each coupon was good for six free Actiq lozenges) and encouraging prescribers to try Actiq on their non-cancer patients.[144]

[144] *Id.*

303. Cephalon's efforts paid off. In 2000, Actiq generated $15 million in sales.[145] By 2002, it attributed a 92% increase in Actiq sales to "a dedicated sales force for ACTIQ" and "ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists."[146] By 2005, Actiq's total sales had spiked to $412 million, making it (a drug approved for only a narrow customer base) Cephalon's second-bestselling drug. By the end of 2006, Actiq's sales had exceeded $500 million.[147]

304. Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. Results of the ImpactRx Survey suggested that "more than 80 percent of patients who use[d] the drug don't have cancer."[148]

b. Government Investigations Found Cephalon Falsely Marketed Actiq for Off-Label Uses

305. Beginning in or about 2003, former Cephalon employees filed four whistleblower lawsuits claiming the company had wrongfully marketed Actiq for unapproved, off-label uses. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay $425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Cephalon trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak

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[145] *Id.*

[146] Cephalon, Inc. Annual Report (Form 10-K) (Mar. 31, 2003), https:// www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm at 28.

[147] Carreyrou, *Narcotic Lollipop*, *supra* n.135.

[148] *Id.*

to physicians about off-label uses of the three drugs and funded CME to promote off-label uses. Specifically, the DOJ stated:

> From 2001 through at least 2006, ***Cephalon was allegedly promoting [Actiq] for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy. Cephalon also promoted Actiq for use in patients who were not yet opioid-tolerant, and for whom it could have life-threatening results***.[149]

306. Then-acting U.S. Attorney Laurie Magid commented on the dangers of Cephalon's unlawful practices:

> "***This company subverted the very process put in place to protect the public from harm, and put patients' health at risk for nothing more than boosting its bottom line***. People have an absolute right to their doctors' best medical judgment. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved."[150]

307. Upon information and belief, documents uncovered in the government's investigations confirm that Cephalon directly targeted non-oncology practices and pushed its sales representatives to market Actiq for off-label use. For instance, the government's investigations confirmed:

- Cephalon instructed its sales representatives to ask non-cancer doctors whether they have the potential to treat cancer pain. Even if the doctor answered "no," a decision tree provided by Cephalon instructed the sales representatives to give these physicians free Actiq coupons;
- Cephalon targeted neurologists in order to encourage them to prescribe Actiq to patients with migraine headaches;
- Cephalon sales representatives utilized the assistance of outside pain management specialists when visiting non-cancer physicians to pitch Actiq. The pain

[149] Press Release, U.S. Department of Justice, Pharmaceutical Company Cephalon To Pay $425 Million For Off-Label Drug Marketing (Sept. 29, 2008), https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonrelease.pdf.

[150] *Id*.

management specialist would falsely inform the physician that Actiq does not cause patients to experience a "high" and carries a low risk of diversion toward recreational use;

- Cephalon set sales quotas for its sales and marketing representatives that could not possibly have been met solely by promoting Actiq for its FDA-approved indication;
- Cephalon promoted the use of higher doses of Actiq than patients required by encouraging prescriptions of the drug to include larger-than-necessary numbers of lozenges with unnecessarily high doses of fentanyl; and
- Cephalon promoted Actiq for off-label use by funding and controlling CME seminars that promoted and misrepresented the efficacy of the drug for off-label uses such as treating migraine headaches and for patients not already opioid-tolerant.[151]

308. Still, the letters, the FDA's safety alert, DOJ and state investigations and the settlement seemed to have had little impact on Cephalon as it continued its deceptive marketing strategy for both Actiq and Fentora.

c. Cephalon Falsely and Aggressively Marketed Cancer Drug Fentora to Non-Cancer Treating Physicians

309. From the time it first introduced Fentora to the market in October 2006, Cephalon targeted non-cancer doctors, falsely represented Fentora as a safe, effective off-label treatment for non-cancer pain and continued its disinformation campaign about the safety and non-addictiveness of Fentora specifically and opioids generally. In fact, Cephalon targeted the same pain specialists and non-oncologists that it had targeted with its off-label marketing of Actiq, simply substituting Fentora.

[151] John Carreyrou, *Cephalon Used Improper Tactics to Sell Drug, Probe Finds*, Wall St. J., Nov. 21, 2006, at B1 (hereinafter "Carreyrou, *Cephalon Used Improper Tactics*").

310. During an investor earnings call shortly after Fentora's launch, Cephalon's chief executive officer ("CEO") described the "opportunity" presented by the use of Fentora for non-cancer pain:

> ***The other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower back pain and breakthrough neuropathic pain***.
>
> * * *
>
> Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%.
>
> We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and wellbeing and the exciting growth potential that it has for Cephalon.
>
> In summary, we have had a strong launch of FENTORA and continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last seven years. In the future, with new and broader indications and a much bigger field force presence, the opportunity that FENTORA represents is enormous.[152]

d. The FDA Warned Cephalon Regarding its False and Off-Label Marketing of Fentora

311. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: "Fentora should not be used to treat any type of short-term pain."[153]

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[152] Seeking Alpha, Transcript of Q1 2007 Cephalon, Inc. Earnings Conference Call, May 1, 2007, http://seekingalpha.com/article/34163-cephalon-q1-2007-earnings-call-transcript?all=true&find =Q1% 2B2007%2BCephalon%2BMay%2B1%2C% 2B2007 at 6-7.

[153] Press Release, U.S. Food & Drug Administration, Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets) (Sept. 26, 2007), https://wayback.archive-

312. Nevertheless, in 2008, Cephalon pushed forward to expand the target base for Fentora and filed a supplemental drug application requesting FDA approval of Fentora for the treatment of non-cancer BTP. In the application and supporting presentations to the FDA, Cephalon admitted both that it knew the drug was heavily prescribed for off-label use and that the drug's safety for such use had never been clinically evaluated.[154] An FDA advisory committee lamented that Fentora's existing risk management program was ineffective and stated that Cephalon would have to institute a risk evaluation and mitigation strategy for the drug before the FDA would consider broader label indications. In response, Cephalon revised Fentora's label and medication guide to add strengthened warnings.

313. But in 2009, the FDA once again informed Cephalon that the risk management program was not sufficient to ensure the safe use of Fentora for already approved indications.

314. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case." Rather, Fentora was only indicated for those who were already opioid tolerant. It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

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it.org/7993/20170406045231/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm.

[154] *FENTORA (fentanyl buccal tablet) CII, Joint Meeting of Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisory Committee*, U.S. Food & Drug Administration (May 6, 2008), https://wayback.archive-it.org/7993/20170405034240/https://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4356s2-03-Cephalon.pdf.

315. Flagrantly disregarding the FDA's refusal to approve Fentora for non-cancer BTP and its warning against marketing the drug for the same, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq.

316. For example, on January 13, 2012, Cephalon published an insert in *Pharmacy Times* titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."[155]

e. Cephalon Funded False Publications and Presentations

317. In addition to its direct marketing, Cephalon indirectly marketed through third parties to change the way doctors viewed and prescribed opioids – disseminating deceptive messages that opioids were safe for the treatment of chronic, long-term pain, that they were non-addictive and that they were woefully under-prescribed to the detriment of patients who were needlessly suffering. It did so by sponsoring pro-opioid front groups, misleading prescription guidelines, articles and CME programs, and it paid physicians thousands of dollars every year to publicly opine that opioids were safe, effective and non-addictive for a wide variety of uses.

318. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC ("Medscape") and which disseminated false and misleading information to physicians in the County.

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[155] *An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Bucall Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)*, Pharmacy Times (Jan. 13, 2012), http://www.pharmacytimes.com/publications/issue/2012/january2012/r514-jan-12-rems.

319. For example, a 2003 Cephalon-sponsored CME presentation titled "Pharmacologic Management of Breakthrough or Incident Pain," posted on Medscape in February 2003, teaches:

> ***[C]hronic pain is often undertreated, particularly in the noncancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse***.[156]

320. Another Cephalon-sponsored CME presentation titled "Breakthrough Pain: Treatment Rationale with Opioids" was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor with interests in "previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis." He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using "targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway."157 The doctor lists fentanyl as one of the most effective opioids available for treating BTP, describing its use as an expected and normal part of the pain management process. Nowhere in the CME presentation is cancer or cancer pain mentioned.

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[156] Michael J. Brennan, *et al.*, *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape, http://www.medscape.org/viewarticle/449803 (last visited February 20, 2018).

[157] Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, http://www.medscape.org/viewarticle/461612 (last visited February 20, 2018).

321. Dr. Stephen H. Landy ("Landy") authored a 2004 CME manuscript available on Medscape titled "Oral Transmucosal Fentanyl Citrate for the Treatment of Migraine Headache Pain In Outpatients: A Case Series." The manuscript preparation was supported by Cephalon. Landy describes the findings of a study of fentanyl citrate for the use of migraine headache pain and concluded that "OTFC rapidly and significantly relieved acute, refractory migraine pain in outpatients . . . and was associated with high patient satisfaction ratings."[158] Based on an analysis of publicly available data, Cephalon paid Landy approximately $190,000 in 2009-2010 alone, and in 2015-2016, Cephalon paid Landy another $75,000.

322. In 2006, Cephalon sponsored a review of scientific literature to create additional fentanyl-specific dosing guidelines titled "Evidence-Based Oral Transmucosal Fentanyl Citrate (OTFC®) Dosing Guidelines."[159] The article purports to review the evidence for dosing and efficacy of oral transmucosal fentanyl citrate in the management of pain and produce dosing guidelines in both cancer and non-cancer patients. In pertinent part, it states:

> Oral transmucosal fentanyl citrate has a proven benefit in treating cancer-associated breakthrough pain in opioid-tolerant patients with cancer, which is the Food and Drug Administration (FDA)-approved indication for Actiq. ***Pain medicine physicians have also used OTFC successfully to provide rapid pain relief in moderate to severe noncancer pain in both opioid-tolerant and opioid-nontolerant patients***.[160]

323. Deeper into the article, the authors attempt to assuage doctors' concerns regarding possible overdose and respiratory distress in non-cancer patients by arguing "***[t]here is no evidence***

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[158] Stephen H. Landy, *Oral Transmucosal Fentanyl Citrate for the Treatment of Migraine Headache Pain In Outpatients: A Case Series*, 44(8) Headache (2004), http://www.medscape.com/viewarticle/488337_2.

[159] Gerald M. Aronoff, *et al.*, *Evidence-Based Oral Transmucosal Fentanyl Citrate (OTFC) Dosing Guidelines*, 6(4) Pain Med. 305-14 (2005).

[160] *Id*.

that opioid safety and efficacy differs in opioid-tolerant patients with chronic noncancer pain."

Regarding the use of fentanyl to treat non-opioid-tolerant patients, the article's authors stated:

> Alternatively, ***OTFC might also be used cautiously and safely for acute pain experienced by patients who are not opioid tolerant. Parenteral opioids are routinely used for acute pain in patients who are not opioid tolerant***. Examples include episodic pain (i.e., refractory migraine pain, recurrent renal calculi, etc.) and acute pain that follows surgery, trauma, or painful procedures (burn dressing change, bone marrow aspiration, lumbar puncture). Assuming that clinical experience with IV morphine in patients who are not opioid tolerant can be extrapolated, OTFC should be safe and efficacious in such settings as well.[161]

324. Through its sponsorship of the FSMB's "Responsible Opioid Prescribing: A Physician's Guide", Cephalon continued to encourage the prescribing of opioid medication to "reverse . . . and improve" patient function, attributing patients' displays of traditional drug-seeking behaviors as merely "pseudoaddiction."

325. Cephalon also disseminated its false messaging through speakers' bureaus and publications. For example, at an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results." The presentation's agenda description states: "Most patients with chronic pain experience episodes of breakthrough pain (BTP), yet no currently available pharmacologic agent is ideal for its treatment." The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the "[i]nterim results of this study suggest that FEBT is safe and well-tolerated in patients with chronic pain and BTP."

326. Cephalon sponsored another CME activity written by Webster and M. Beth Dove titled "Optimizing Opioid Treatment for Breakthrough Pain" and offered on Medscape from

[161] *Id*.

September 28, 2007 through December 15, 2008. The CME activity teaches that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating BTP than pure opioid analgesics because of dose limitations on the non-opioid component.[162]

327. Perry G. Fine authored a Cephalon-sponsored CME article titled "Opioid-Based Management of Persistent and Breakthrough Pain," with Drs. Christine A. Miaskowski and Michael J. Brennan. Cephalon paid to have this CME article published in a "Special Report" supplement of the journal *Pain Medicine News* in 2009.[163] The CME article targeted a wide variety of non-oncologist healthcare providers who treat patients with chronic pain with the objective of educating "health care professionals about a semi-structured approach to the opioid-based management of persistent and breakthrough pain," including the use of fentanyl. The CME article purports to analyze the "combination of evidence- and case-based discussions" and ultimately concludes:

> Chronic pain is a debilitating biopsychosocial condition prevalent in both cancer and noncancer pain populations. . . . Opioids have an established role in pain related to cancer and other advanced medical illnesses, as well as an increasing contribution to the long-term treatment of carefully selected and monitored patients with certain [chronic noncancer pain] conditions. ***All individuals with chronic, moderate to severe pain associated with functional impairment should be considered for a trial or opioid therapy, although not all of them will be selected***.[164]

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[162] Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, Medscape, http://www.medscape.org/viewarticle/563417_6 (last visited February 20, 2018).

[163] Perry G. Fine, *et al*., *Opioid-Based Management of Persistent and Breakthrough Pain*, Special Report (2009), https://www.yumpu.com/en/document/ view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain/9.

[164] *Id*.

328. Along with Purdue, Cephalon sponsored APF's guide, which warned against the purported ***under***-prescribing of opioids, taught that addiction is ***rare*** and suggested that opioids have "***no ceiling dose***" and are therefore, the most appropriate treatment for severe pain.

329. A summary of the February 12-16, 2008 AAPM annual meeting reinforced the message, promoted both by the AAPM and the APS, that "the undertreatment of pain is unjustified." It continues:

> ***Pain management is a fundamental human right*** in all patients not only with acute postoperative pain but also ***in patients suffering from chronic pain***. Treating the underlying cause of pain does not usually treat all of the ongoing pain. Minimal pathology with maximum dysfunction remains the enigma of chronic pain. Chronic pain is only recently being explored as a complex condition that requires individual treatment and a multidisciplinary approach. It is considered to be a disease entity.[165]

330. Cephalon was one of several opioid manufacturers who collectively paid 14 of the 21 panel members who drafted the 2009 APS-AAPM opioid treatment guidelines.[166]

331. In the March 2007 article titled "Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate,"[167] published in the nationally circulated journal *Pain Medicine*, physicians paid by Cephalon (including Webster) described the results of a Cephalon-sponsored study seeking to expand the definition of BTP to the chronic, non-cancer setting. The authors stated that the "OTFC has been shown to relieve BTP more rapidly than conventional oral, normal-

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[165] Mohamed A. Elkersh & Zahid H. Bajwa, *Highlights From the American Academy of Pain Medicine 24th Annual Meeting*, 2(1) Advances in Pain Management 50-52 (2008).

[166] *See* Chou, *Clinical Guidelines*, *supra* n.59.

[167] Donald R. Taylor, *et al.*, *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ)*, 8(3) Pain Med. 281-88 (Mar. 2007).

release, or 'short acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of noncancer pain patients."[168] The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

> In summary, BTP appears to be a clinically important condition in patients with ***chronic noncancer pain*** and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP ***and the potential benefits of BTP-specific therapy*** suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.[169]

332. Cephalon also sponsored, through an educational grant, the regularly published journal *Advances in Pain Management*. In a single 2008 issue of the journal, there are numerous articles from Portenoy, Dr. Steven Passik ("Passik"), Dr. Kenneth L. Kirsh ("Kirsh") and Webster, all advancing the safety and efficacy of opioids. In an article titled "Screening and Stratification Methods to Minimize Opioid Abuse in Cancer Patients," Webster expresses disdain for the prior 20 years of opioid phobia.

333. In another article from the same issue, "Appropriate Prescribing of Opioids and Associated Risk Minimization," Passik and Kirsh state: "[c]hronic pain, currently experienced by approximately 75 million Americans, is becoming one of the biggest public health problems in the US." They assert that addiction is rare, that "[m]ost pain specialists have prescribed opioids for long periods of time with success demonstrated by an improvement in function" and that then-

[168] *Id.*

[169] *Id.*

recent work had shown "that opioids do have efficacy for subsets of patients who can remain on them long term and have very little risk of addiction."[170]

334. In November 2010, Fine and others published an article presenting the results of another Cephalon-sponsored study titled "Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study."[171] In that article, Fine explained that the 18-month "open-label" study "assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for persistent [sic] noncancer pain." The article acknowledges that: (a) "[t]here has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades"; (b) the "widespread acceptance" had led to the publishing of practice guidelines "to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain"; and (c) those guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain."[172]

335. They conclude: "[T]he safety and tolerability profile of [Fentora] in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases,

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[170] Steven D. Passik & Kenneth L. Kirsh, *Appropriate Prescribing of Opioids and Associated Risk Minimization*, 2(1) Advances in Pain Management 9-16 (2008).

[171] Perry G. Fine, *et al.*, *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) J. Pain & Symptom Management 747-60 (Nov. 2010).

[172] *Id.*

predictable, manageable, and tolerable." They also conclude that the number of abuse-related events was "small."[173]

336. From 2000 forward, Cephalon has paid doctors nationwide millions of dollars for programs relating to its opioids, many of whom were not oncologists and did not treat cancer pain. These doctors included Portenoy, Webster, Fine, Passik, Kirsh, Landy and others.

337. Cephalon's payments to doctors have resulted in studies that support its sales but, on closer examination, are biased or irreparably flawed. For instance, and upon information and belief, the governmental whistleblower investigation into Actiq revealed that two studies touted by Cephalon had tested fewer than 28 patients and had no control group whatsoever.[174] A 2012 article evaluating the then-current status of transmucosal fentanyl tablet formulations for the treatment of BTP in cancer patients noted that clinical trials to date used varying criteria, that "the approaches taken . . . [did] not uniformly reflect clinical practice" and that "the studies ha[d] been sponsored by the manufacturer and so ha[d] potential for bias."[175]

5. Insys

338. Insys markets, sells, and distributes the following pharmaceutical drug in the County:

Subsys (fentanyl)	Fentanyl sublingual spray; semi-synthetic opioid agonist, approved in 2012.

[173] *Id*.

[174] Carreyrou, *Cephalon Used Improper Tactics*, *supra* n.148.

[175] Eric Prommer & Brandy Fleck, *Fentanyl Transmucosal Tablets: Current Status in the Management of Cancer-related Breakthrough Pain*, 2012(6) Patient Preference and Adherence 465-75 (June 25, 2012).

339. Subsys is indicated "for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain."[176] The indication also specifies that "SUBSYS is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain." In addition, the indication provides that "[p]atients must remain on around-the-clock opioids when taking SUBSYS." Subsys is contraindicated for, among other ailments, the "[m]anagement of acute or postoperative pain including headache/migraine and dental pain." It is available in 100 mcg, 200 mcg, 400 mcg, 600 mcg and 800 mcg dosage strengths.

340. Insys' revenue is derived almost entirely from Subsys. According to its Form 10-K for 2015, Insys reported revenues of $331 million. Of that total, $329.5 million was derived from sales of Subsys.

341. According to Dr. Andrew Kolodny, executive director of Physicians for Responsible Opioid Prescribing and chief medical officer of the Phoenix House Foundation, fentanyl products are "'the most potent and dangerous opioids on the market.'"[177]

342. The dangers associated with Subsys are reflected by its extremely limited and specific indication, as it is approved solely for BTP in cancer patients already receiving opioids for persistent cancer-related pain.

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[176] The indication provides that "[p]atients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer."

[177] Dina Gusovsky, *The Pain Killer: A Drug Company Putting Profits Above Patients*, CNBC (Nov. 5, 2015, 10:13 AM), http://www.cnbc.com/2015/11/04/the-deadly-drug-appeal-of-insys-pharmaceuticals.html.

343. Despite Subsys' limited indication and the potent danger associated with fentanyl, Insys falsely and misleadingly marketed Subsys to doctors as an effective treatment for back pain, neck pain and other off-label pain conditions.[178] Moreover, as of June 2012, Insys defined BTP in cancer patients to include mild pain: a "flare of ***mild-to***-severe pain in patients with otherwise stable persistent pain," based on a misleading citation to a paper written by Portenoy.[179] Insys trained and instructed its sales representatives to use the false definition of breakthrough pain and specifically to use a core visual aid, including the improper definition, whenever they detailed Subsys to a healthcare provider or provider's office.

344. According to a 2014 article in *The New York Times*, only 1% of prescriptions for Subsys were written by oncologists. Approximately half the prescriptions were written by pain specialists, with others written by other specialists including dentists and podiatrists.[180]

a. The Indictment of Insys Executives and Arrest of Its Founder

345. On December 8, 2016, several former Insys executives were arrested and indicted for conspiring to bribe practitioners in numerous states, many of whom operated pain clinics, in order to induce them to prescribe Subsys. In exchange for bribes and kickbacks, the practitioners

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[178] *In the Matter of Insys Therapeutics, Inc.*, Notice of Unlawful Trade Practices and Proposed Resolution (July 10, 2015), https://www.documentcloud.org/ documents/2195731-insysdoj.html.

[179] Portenoy's paper, "Breakthrough Pain: Definition, Prevalence and Characteristics," which was featured in the 1990 issue of *Pain*, actually defined breakthrough pain as "a transitory increase in pain to greater than moderate intensity (that is, to an intensity of 'severe' or 'excruciating') . . . on a baseline pain of moderate intensity or less." Russell K. Portenoy & Neil A. Hagen, *Breakthrough Pain: Definition, Prevalence and Characteristics*, 41(3) Pain 273-81 (July 1990).

[180] Katie Thomas, *Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller*, N.Y. Times (May 13, 2014), https://www.nytimes.com/2014/05/14/ business/doubts-raised-about-off-label-use-of-subsys-a-strong-painkiller.html?action= click&contentCollection=Business%20Day&region=Footer&module=MoreInSection&pgtype=Blogs&_r=2.

wrote large numbers of prescriptions for patients, most of whom were not diagnosed with cancer.[181]

346. The indictment alleged that the former executives conspired to mislead and defraud health insurance providers, who were reluctant to approve payment for Subsys when it was prescribed for patients without cancer. In response, the former executives established a "reimbursement unit" at Insys, which was dedicated to assisting physicians by obtaining prior authorization for prescribing Subsys directly from insurers and pharmacy benefit managers. Insys' reimbursement unit employees were told to inform agents of insurers and pharmacy benefit managers that they were calling "from" or that they were "with" the doctor's office, or that they were calling "on behalf of" the doctor.

347. The executive defendants in the indictment are Insys' former CEO and president, former vice president of sales, former national director of sales, former vice president of managed markets and several former regional sales directors. On October 26, 2017, the billionaire founder, CEO, and chairman of Insys, John Kapoor, who owns approximately 70% of the company, was also charged with fraud and racketeering and was accused of offering bribes to doctors to write large numbers of prescriptions for Subsys. Most of the patients who received the medication did not have cancer. [182]

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[181] Press Release, U.S. Attorney's Office for the District of Massachusetts, Pharmaceutical Executives Charged in Racketeering Scheme (Dec. 8, 2016), https://www.justice.gov/usao-ma/pr/pharmaceutical-executives-charged-racketeering-scheme (hereinafter "*Insys* Indictment Press Release"); *United States v. Babich, et al.*, No. 1:16-cr-10343-ADB, Dkt. No. 1 (D. Mass. Dec. 6, 2016), https://www.justice.gov/usao-ma/press-release/file/916681/download (hereinafter "*Insys* Indictment").

[182] Michela Tindera, *Opioid Billionaire Arrested on Racketeering Charges*, Forbes (October 26, 2017) (https://www.forbes.com/sites/michelatindera/2017/10/26/opioid-billionaire-arrested-on-racketeering-charges/#1af3f9076a00) (hereinafter "Tindera, *Opioid Billionaire Arrested*").

348. The charges against all seven executives include alleged violations of the federal Anti-Kickback Law, the federal Racketeer Influenced and Corrupt Organizations ("RICO") statute and conspiracy to commit wire and mail fraud, as well as allegations of bribery and defrauding insurers. If found guilty, the defendants face possible sentences of up to 20 years for conspiracy to commit RICO and conspiracy to commit mail and wire fraud, as well as a fine of $250,000 or twice the amount of the pecuniary gain or loss. For the charge of conspiracy to violate the Anti-Kickback Law, the defendants face a sentence of up to five years in prison and a $25,000 fine.

349. The indictment details a coordinated, centralized scheme by Insys to illegally drive profits. The company defrauded insurers from a call center at corporate headquarters where Insys employees, acting at the direction of Insys' former CEO and vice president of managed markets, disguised their identity and the location of their employer and lied about patient diagnoses, the type of pain being treated and the patient's course of treatment with other medication.

350. Harold Shaw, special agent in charge of the FBI Boston field division, said in a statement, "As alleged, these executives created a corporate culture at Insys that utilized deception and bribery as an acceptable business practice, deceiving patients, and conspiring with doctors and insurers."[183]

b. Insys Targeted Non-Cancer Treating Physicians and Funded False Publications and Presentations

351. As set forth in the above-referenced indictment, Insys targeted and bribed practitioners in a number of ways. Insys bribed Subsys prescribers through strategic hires and by employing sales representatives and other employees at practitioners' behest, with the expectation that such hires would provide inroads with key practitioners. Insys also bribed practitioners

[183] Tindera, *Opioid Billionaire Arrested*, *supra* n.179.

through a sham speakers' bureau that was purportedly intended to increase brand awareness using peer-to-peer educational lunches and dinners.

352. Specifically, in June 2012, former executives began using in-person meetings, telephone calls and texts to inform Insys sales representatives that the key to sales was using the speakers' bureau to pay practitioners to prescribe Subsys. As one of the company's vice presidents for sales texted one of his sales representatives about potential physicians for the speakers' bureau: "[t]hey do not need to be good speakers, they need to write a lot of [Subsys prescriptions]." The former Insys executives actively recruited physicians known to have questionable prescribing habits for these speakers' bureaus.[184]

353. The speakers' bureaus were often just social gatherings at high-priced restaurants involving neither education nor presentations. Frequently, they involved repeat attendees, including physicians not licensed to prescribe Subsys. Many of the speakers' bureaus had no attendees; sales representatives were instructed to falsely list names of attendees and their signatures on Insys' sign-in sheets.

354. Insys made thousands of payments to physicians nationwide, including to physicians in the County, for participating on these speakers' bureaus and for other services.

355. Moreover, the executives are charged with targeting practitioners who prescribed Subsys not only for cancer pain, but for all pain.

356. As set forth in the indictment, at one national speakers' bureau in or about 2014, Insys' then-vice president of sales stated:

> "These [doctors] will tell you all the time, well, I've only got like eight patients with cancer. Or, I only have, like, twelve patients that are on a rapid-onset opioids [sic]. Doc, I'm not talking about any of those patients. I don't want any of those

[184] *Insys* Indictment Press Release, *supra* n.178.

> patients. That's, that's small potatoes. That's nothing. That's not what I'm here doing. I'm here selling [unintelligible] for the breakthrough pain. If I can successfully sell you the [unintelligible] for the breakthrough pain, do you have a thousand people in your practice, a thousand patients, twelve of them are currently on a rapid-onset opioids [sic]. ***That leaves me with at least five hundred patients that can go on this drug.***"[185]

357. Moreover, when agents of insurers or pharmacy benefit managers asked if a patient was being treated for BTP in cancer patients, Insys' reimbursement unit employees were instructed to answer using a written script, sometimes called "the spiel": "'The physician is aware that the medication is intended for the management of breakthrough pain in cancer patients. The physician is treating the patient for their pain (or breakthrough pain, whichever is applicable).'"[186]

358. Insys' former executives also tracked and internally circulated the number of planned and completed speakers' bureau events for each speaker, as well as the number of Subsys prescriptions each speaker wrote, the percentage of such prescriptions compared to those written for Subsys' competitor drugs, the total amount of honoraria paid to each speaker and, for a period of time, an explicit calculation of the ratio of return on investment for each speaker. When a speaker did not write an appropriate number of Subsys prescriptions, as determined by Insys, the number of future events for which that speaker would be paid would be reduced unless and until he or she wrote more Subsys prescriptions.

359. In a press release issued when the indictment was announced, the Massachusetts U.S. Attorney, Carmen M. Ortiz, stated: "'I hope that today's charges send a clear message that

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[185] *Insys* Indictment, *supra* n.178, at 15.

[186] *Id*. at 44.

we will continue to attack the opioid epidemic from all angles, whether it is corporate greed or street level dealing.'"[187]

360. In the same press release, the FBI Special Agent in Charge of the Boston Field Division, Harold H. Shaw, linked the allegations to the national opioid epidemic:

> "***As alleged, top executives of Insys Therapeutics, Inc. paid kickbacks and committed fraud to sell a highly potent and addictive opioid that can lead to abuse and life threatening respiratory depression . . . . In doing so, they contributed to the growing opioid epidemic and placed profit before patient safety. These indictments reflect the steadfast commitment of the FBI and our law enforcement partners to confront the opioid epidemic impacting our communities, while bringing to justice those who seek to profit from fraud or other criminal acts***."[188]

361. The Special Agent in Charge at the Defense Criminal Investigative Service in the Northeast Field Office, Craig Rupert, commented specifically on the effect the criminal activities had on members of the military: "'Causing the unnecessary use of opioids by current and retired U.S. military service members shows disregard for their health and disrespect for their service to our country . . . .'"[189]

6. Mallinckrodt

362. Mallinckrodt markets, sells, and distributes pharmaceutical drugs in the County. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

363. Among the drugs it distributes are the following:

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[187] *Insys* Indictment Press Release, *supra* n.178.

[188] *Id*.

[189] *Id*.

Exalgo (hydromorphone hydrochloride extended release)	Opioid agonist indicated for opioid-tolerant patients for management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options (*e.g.*, non-opioid analgesics) are inadequate. The FDA approved the 8, 12, and 16 mg tablets of Exalgo in March 2010 and 32 mg tablet in August 2012.
Roxicodone (oxycodone hydrochloride)	Brand-name instant-release form of oxycodone hydrochloride. Indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Acquired from Xanodyne Pharmaceuticals in 2012. Strengths range up to 30 mg per pill. Nicknames include Roxies, blues, and stars.
Xartemis XR (oxycodone hydrochloride and acetaminophen)	The FDA approved Xartemis XR in March 2014 for the management of acute pain severe enough to require opioid treatment and in patients for whom alternative treatment options are ineffective, not tolerated or would otherwise be inadequate. It was the first extended-release oral combination of oxycodone and acetaminophen.
Methadose (methadone hydrochloride)	Branded generic product. Opioid agonist indicated for treatment of opioid addiction.
Morphine sulfate extended release	Generic product.
Fentanyl extended release	Generic product.
Fentanyl citrate	Generic product.
Oxycodone and acetaminophen	Generic product.
Hydrocodone bitartrate and acetaminophen	Generic product.
Hydromorphone hydrochloride	Generic product.
Hydromorphone hydrochloride extended release	Generic product.
Naltrexone hydrochloride	Generic product.
Oxymorphone hydrochloride	Generic product.
Methadone hydrochloride	Generic product.
Oxycodone hydrochloride	Generic product.

364. Mallinckrodt purchased Roxicodone from Xanodyne Pharmaceuticals in 2012.[190]

365. Mallinckrodt debuted Xartemis (MNK-795) at the September 4-7, 2013 PAINWeek in Las Vegas.

a. Mallinckrodt Funded False Publications and Presentations

366. Like several of the other Manufacturer Defendants, Mallinckrodt provided substantial funding to purportedly neutral organizations, which disseminated false messaging about opioids.

367. For example, until at least February 2009, Mallinckrodt provided an educational grant to Pain-Topics.org, a now-defunct website that touted itself as "a noncommercial resource for healthcare professionals, providing open access to clinical news, information, research, and education for a better understanding of evidence-based pain-management practices."[191]

368. Among other content, the website included a handout titled "Oxycodone Safety Handout for Patients," which advised practitioners that: "Patients' fears of opioid addiction should be dispelled."[192] The handout included several false and misleading statements concerning the risk of addiction associated with prescription opioids:

Will you become dependent on or addicted to oxycodone?

- After a while, oxycodone causes physical dependence. That is, if you suddenly stop the medication you may experience uncomfortable

[190] *Mallinckrodt Announces Agreement with Xanodyne to Purchase Roxicodone*, Bus. Wire (Aug. 23, 2012), http://www.businesswire.com/news/ home/20120823005209/en/Mallinckrodt-Announces-Agreement-Xanodyne-Purchase-Roxicodone%C2%AE.

[191] *Pain Treatment Topics*, Pain-Topics.org, https://web.archive.org/web/20070104235709 http://www.pain-topics.org:80/ (last visited February 20, 2018).

[192] Lee A. Kral & Stewart B. Leavitt, *Oxycodone Safety Handout for Patients*, Pain-Topics.Org (June 2007), http://paincommunity.org/blog/wp-content/uploads/ Oxycodone/Handout.pdf.

> withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.
>
> - This is not the same as addiction, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.[193]

369. Additionally, the FAQ section of Pain-Topics.org contained the following false and misleading information downplaying the dangers of prescription opioid use:

> **Pseudoaddiction** – has been used to describe aberrant patient behaviors that may occur when pain is undertreated (AAPM 2001). Although this diagnosis is not supported by rigorous investigation, it has been widely observed that patients with unrelieved pain may become very focused on obtaining opioid medications, and may be erroneously perceived as "drug seeking." Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated. Along with this, two related phenomena have been described in the literature (Alford et al. 2006):
>
> **Therapeutic dependence** – sometimes patients exhibit what is considered drug-seeking because they fear the reemergence of pain and/or withdrawal symptoms from lack of adequate medication; their ongoing quest for more analgesics is in the hopes of insuring a tolerable level of comfort.
>
> **Pseudo-opioid-resistance** – other patients, with adequate pain control, may continue to report pain or exaggerate its presence, as if their opioid analgesics are not working, to prevent reductions in their currently effective doses of medication.
>
> Patient anxieties about receiving inadequate pain control can be profound, resulting in demanding or aggressive behaviors that are misunderstood by healthcare practitioners and ultimately detract from the provision of adequate pain relief.[194]

370. Another document available on the website, "Commonsense Oxycodone Prescribing & Safety," falsely suggests that generic oxycodone is less prone to abuse and diversion than branded oxycodone: "Anecdotally, it has been observed that generic versions of popularly

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[193] *Id.*

[194] *FAQs*, Pain-Topics.org, https://web.archive.org/web/20070709031530/ http://www.pain-topics.org:80/faqs/index1.php#tolerance.

abused opioids usually are less appealing; persons buying drugs for illicit purposes prefer brand names because they are more recognizable and the generics have a lower value 'on the street,' which also makes them less alluring for drug dealers."[195]

371. In November 2016, Mallinckrodt paid Dr. Scott Gottlieb ("Gottlieb"), the new commissioner of the FDA, $22,500 for a speech in London, shortly after the U.S. presidential election.[196] Gottlieb has also received money from the Healthcare Distribution Alliance ("HDA"), an industry-funded organization that pushes the agenda of large pharmaceutical wholesalers, and he has often criticized efforts aimed at regulating the pharmaceutical opioid market.[197]

372. Mallinckrodt also made thousands of payments to physicians nationwide, including to physicians in the County.

373. Exalgo, Roxicodone and Xartemis XR have been widely prescribed in the County.

b. The DEA Investigates Suspicious Orders

374. In 2008, the DEA and federal prosecutors launched an investigation into Mallinckrodt, charging that the company ignored red flags and supplied – and failed to report – suspicious orders for its generic oxycodone between 2008 and 2012.[198] The U.S. Attorney's office in Detroit, handled the case. The investigation uncovered that from 2008 to 2012, Mallinckrodt

[195] Lee A. Kral & Stewart B. Leavitt, *Oxycodone Safety Handout for Patients*, Pain-Topics.Org (June 2007), http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.

[196] Lee Fang, *Donald Trump's Pick to Oversee Big Pharma Is Addicted to Opioid-Industry Cash*, Intercept (Apr. 4, 2017, 2:15 PM), https://theintercept.com/ 2017/04/04/scott-gottlieb-opioid/.

[197] *Id.*

[198] Lenny Bernstein & Scott Higham, *The government's struggle to hold opioid manufacturers accountable*, Wash. Post (Apr. 2, 2017), https://www.washingtonpost.com/graphics/ investigations/dea-mallinckrodt/?utm_ term=.7ce8c975dd86.

sent, for example, 500 million tablets of oxycodone into a single state.[199] According to the internal government documents obtained by The Washington Post, Mallinckrodt's failure to report could have resulted in "nearly 44,000 federal violations and exposed it to $2.3 billion in fines."[200]

375. Despite learning from the DEA that generic opioids seized in a Tennessee drug operation were traceable to one of its distributors, Sunrise Wholesale ("Sunrise"), Mallinckrodt in the following six weeks sent 2.1 million tablets of oxycodone to Sunrise. In turn, Sunrise sent at least 92,400 oxycodone tablets to a single doctor over an 11-month period, who, in one day, prescribed 1,000 to a single patient.[201]

376. According to documents obtained by the Washington Post, investigators also found "scores of alleged violations" at Mallinckrodt's plant in Hobart, New York. Those violations included the failure to keep accurate records, to document transfers of drugs and to secure narcotics.[202]

377. During the DEA's investigation, Mallinckrodt sponsored the HDA (known as the Healthcare Distribution Management Association until 2016), an industry-funded organization that represents pharmaceutical distributors.[203] The HDA initiated the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (enacted April 19, 2016), which requires the DEA to give notice of violations and an opportunity to comply, to pharmacies and distributors, before

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[199] *Id.*

[200] *Id.*

[201] *Id.*

[202] *Id.*

[203] *Sponsors: HDA's Annual Circle Sponsors*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/hda-sponsors (last visited February 20, 2018).

withdrawing licenses. This Act substantially lessened the DEA's ability to regulate manufacturers and wholesalers.[204]

378. In May 2014, Mallinckrodt posted a video titled "Red Flags: Pharmacists Anti-Abuse Video." The video is a thinly veiled attempt to divert responsibility for the opioid epidemic away from manufacturers and wholesalers, and toward individual pharmacists. The video was sponsored by the Anti-Diversion Industry Working Group, which is composed of, among others, McKesson, Mallinckrodt, AmerisourceBergen, and Qualitest—all of whom are conveniently missing from the list of those responsible.[205]

379. In April 2017, Mallinckrodt plc reached an agreement with the DEA and the U.S. Attorneys for the Eastern District of Florida and Northern District of New York to pay $35 million to resolve a probe of its distribution of its opioid medications.[206] Mallinckrodt finalized the settlement on July 11, 2017, agreeing to pay $35 million while admitting no wrongdoing.[207]

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[204] Chris McGreal, *Opioid Epidemic: Ex-DEA Official Says Congress is Protecting Drug Makers*, Guardian (Oct. 31, 2016, 9:26 EDT), https://www.theguardian.com/us-news/2016/oct/31/opioid-epidemic-dea-official-congress-big-pharma.

[205] Mallinckrodt Pharmaceuticals, *Red Flags: Pharmacists Anti-Abuse Video*, YouTube (May 27, 2014), https://www.youtube.com/watch?v=fdv0B210bEk&t=1s.

[206] Linda A. Johnson, *Mallinckrodt to Pay $35M in Deal to End Feds' Opioid Probe*, U.S. News & World Report (Apr. 3, 2017, 6:47 PM), https://www.usnews.com/news/business/articles/2017-04-03/mallinckrodt-to-pay-35m-in-deal-to-end-feds-opioid-probe.

[207] Press Release, U.S. Department of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

E. Each Manufacturer Defendant Violated New Jersey State Laws Pertaining to the Manufacture, Distribution, and Sale of Prescription Drugs.

380. The Manufacturer Defendants violated New Jersey state laws pertaining to the manufacture, distribution, and sale of opioids by failing to, *inter alia*,

(a) design and operate a system to identify suspicious orders of controlled substances and to notify the Drug Control Unit of any suspicious orders. N.J.A.C. § 13:45H-2.4(b);

(b) maintain complete and accurate the records and inventories and file reports regarding the same with the proper regulatory and enforcement body. N.J.A.C. § 13:45H-5.9 – 5.13;

(c) establish and maintain records of all transactions regarding the receipt, distribution or other disposition of all prescription drugs, N.J.A.C. § 24:6B-27;

(d) establish and maintain procedures for reporting counterfeit or suspected counterfeit prescription drugs, or counterfeiting or suspected counterfeiting activities to the department, N.J.A.C. § 24:6B-27;

(e) establish and maintain a system for mandatory reporting to the department of significant shortages or losses of prescription drugs when diversion of prescription drugs is known or suspected, N.J.A.C. § 24:6B-27; and

(f) "establish, maintain and adhere to written policies and procedures for the receipt, security, storage, inventory, transport, shipping and distribution of prescription drugs, including policies and procedures for: identifying, recording and reporting losses or thefts; correcting all errors and inaccuracies in inventories; and implementing and maintaining a continuous quality improvement system," N.J.S.A. § 24:6B-28 (a) and (b).

381. It is foreseeable to each Defendant that failing to adhere to the statutory requirements pertaining to the manufacture, sale, and distribution of prescription opioids listed above would cause harm to the County.

F. The Distributor Defendants Failed to Track and Report Suspicious Sales as Required by New Jersey Law.

382. Manufacturers rely upon distributors to distribute their drugs. The distributors serve as middlemen, sending billions of doses of opioid pain pills to pharmacists, hospitals, nursing homes and pain clinics. According to the CDC, the increased distribution of opioids directly correlates to increased overdose death rates.

383. On October 23, 2017, CBS aired an episode of 60 Minutes featuring former DEA agent Joe Rannazzisi, who blamed the Distributor Defendants for knowingly fueling the opioid epidemic by violating the CSA requirement to report suspicious orders:

> **RANNAZZISI:** This is an industry that's out of control. What they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die.
>
> * * *
>
> This is an industry that allowed millions and millions of drugs to go into bad pharmacies and doctors' offices, that distributed them out to people who had no legitimate need for those drugs.
>
> **[INTERVIEWER]:** Who are these distributors?
>
> **RANNAZZISI:** The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.
>
> **[INTERVIEWER]:** You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> **RANNAZZISI:** That's not an implication, that's a fact. That's exactly what they did.

384. Jim Geldhof, a 40-year veteran of the DEA who ran investigations in the Detroit field office corroborated Rannazzinsi's account, saying that the wholesalers are "absolutely" responsible for the opioids epidemic:

> **[INTERVIEWER]:** These companies are a big reason for this epidemic?
>
> **GELDHOF:** Yeah, absolutely they are. And I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us.

385. Indeed, according to Rannazzisi, the Manufacturer Defendants succeeded in lobbying Congress to strip the DEA of its most potent tool for fighting against diversion and abuse. In 2013, a bill was introduced in the House that "was promoted as a way to ensure that patients had access to the pain medication they needed." What it "really did," however, "was strip the [DEA] of its ability to immediately freeze suspicious shipments of prescription narcotics to keep drugs off U.S. streets." A 2015 Justice Department memo confirmed that the bill "'could actually result in increased diversion, abuse, and public health and safety consequences.'"

386. During the two years the legislation was considered and amended, Defendants and others in the industry spent $102 million lobbying Congress on the bill and other legislation, "claiming the DEA was out of control [and] making it harder for patients to get needed medication." The APA co-signed a letter in support of the legislation. The APA receives funding from numerous industry participants, including defendants Endo, Johnson & Johnson, Mallinckrodt, Purdue, and Cephalon. Metadata associated with the letter co-signed by the APA shows that it was created by Kristen L. Freitas, vice president for federal government affairs at the Healthcare Distributors Alliance – the trade group that represents defendants McKesson, and AmerisourceBergen. Freitas is also a registered lobbyist who lobbied in support of the bill.

1. McKesson

387. McKesson is a wholesale pharmaceutical distributor of controlled and uncontrolled prescription medications, including opioids. It is the largest drug distributor, and the fifth largest company, in the United States. It distributes pharmaceuticals through a network of distribution centers across the country. McKesson ranked fifth on the 2017 Fortune 500 list, with over $192 billion in revenues.

388. McKesson is a distributor of opioids in the County and supplies various pharmacies in the County with an increasing amount of prescription opioid pills.

389. McKesson distribution centers are required to operate in accordance with laws and regulations governing the sale and distribution of Schedule II narcotics, such as opioids, within the State of New Jersey.

390. Federal law requires McKesson to to design and operate a system to disclose suspicious orders of controlled substances, as well as by failing to actually disclose such suspicious orders, as required of "registrants" by the federal CSA, 21 C.F.R. § 1301.74(b).

391. McKesson failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the proper authorities of suspicious orders.

392. In or about 2007, the DEA accused McKesson of failing to report suspicious orders and launched an investigation. In 2008, McKesson entered into a settlement agreement with the DOJ and a memorandum of agreement, agreeing to pay a $13.25 million fine for failure to report suspicious orders of pharmaceutical drugs and promising to set up a monitoring system.

393. As a result, McKesson developed a Controlled Substance Monitoring Program ("CSMP") but nevertheless failed to design and implement an effective system to detect and report "suspicious orders" for controlled substances distributed to its independent and small chain

pharmacy customers – *i.e.*, orders that are unusual in their frequency, size or other patterns. McKesson continued to fail to detect and disclose suspicious orders of controlled substances. It failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers and bypassed suspicious order reporting procedures set forth in the CSMP.

394. In 2013, the DEA again began investigating reports that McKesson was failing to maintain proper controls to prevent the diversion of opioids and accused McKesson of failing to design and use an effective system to detect "suspicious orders" from pharmacies for powerful painkillers such as oxycodone, as required by the Controlled Substances Act.

395. On January 17, 2017, in one of the most severe sanctions ever agreed to by a distributor, McKesson agreed to pay a record $150 million in fines and suspend sales of controlled substances from distribution centers in four states (Colorado, Ohio, Michigan and Florida) to settle allegations that the company violated federal law. According to the DOJ, McKesson continued to fail to report suspicious orders between 2008 and 2012 and did not fully implement or follow the monitoring program. As part of the agreement, McKesson acknowledged that:

> at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA.

396. It is foreseeable to McKesson that failing to design and operate a system to disclose suspicious orders of controlled substances and/or failing to notify the DCU of suspicious orders would cause harm to the County.

2. AmerisourceBergen

397. AmerisourceBergen is a wholesale distributor of pharmaceuticals, including controlled substances and non-controlled prescription medications.

398. AmerisourceBergen is a distributor of opioids in the United States. It handles the distribution of approximately 20% of all pharmaceuticals sold and distributed in the U.S. through a network of 26 pharmaceutical distribution centers.[208] It ranked 11th on the Fortune 500 list in 2017, with over $146 billion in annual revenue.

399. AmerisourceBergen is a distributor of opioids in the County and supplies various pharmacies in Sussex County with an increasing amount of prescription opioid pills.

400. AmerisourceBergen distribution centers are required to operate in accordance with laws and regulations governing the sale and distribution of Schedule II narcotics, such as opioids, within the State of New Jersey.

401. Federal law requires AmerisourceBergen to design and operate a system to disclose suspicious orders of controlled substances, as well as by failing to actually disclose such suspicious orders, as required of "registrants" by the federal CSA, 21 C.F.R. § 1301.74(b).

402. AmerisourceBergen failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the proper authorities of suspicious orders.

403. In 2012, West Virginia sued AmerisourceBergen and other wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, McKesson and others, together shipped 423 million pain pills to West Virginia between 2007 and 2012.[209] AmerisourceBergen itself shipped 80.3 million

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[208] *AmerisourceBergen*, Wikipedia, https://en.wikipedia.org/wiki/AmerisourceBergen (hereinafter "*AmerisourceBergen*") (last visited February 20, 2018).

[209] Eric Eyre, *Drug Firms Poured 780M Painkillers into WV Amid Rise of Overdoses*, Charleston Gazette-Mail (Dec. 17, 2016), http://www.wvgazettemail.com/news-health/20161217/drug-firms-poured-780m-painkillers-into-wv-amid-rise-of-overdoses.

hydrocodone pills and 38.4 oxycodone pills during that time period.[210] Moreover, public documents also demonstrate that that the average dose of each tablet distributed grew substantially during that time period. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit by paying $16 million to the state, with the funds set aside to fund drug treatment programs in order to respond to the opioid addiction crisis.

404. It is foreseeable to AmerisourceBergen that failing to design and operate a system to disclose suspicious orders of controlled substances and/or failing to notify the DCU of suspicious orders would cause harm to the County.

3. Cardinal Health

405. Cardinal Health describes itself as a global integrated healthcare services and products company. It generated $121.5 billion in total revenue during fiscal year 2016 (ended June 30, 2016). It is ranked 15th by revenue on the 2017 Fortune 500 list of top United States companies.

406. Cardinal Health distributes branded and generic pharmaceutical, special pharmaceutical, over-the-counter and consumer products in the United States. Of Cardinal Health's $121.5 billion in revenue during fiscal year 2016, $109.1 billion was derived from the pharmaceutical operating segment.

407. Cardinal Health is a significant distributor of opioids in the United States. Cardinal Health's largest customer is CVS Health ("CVS"), which accounted for 25% of Cardinal Health's fiscal year 2016 revenue. According to its website, CVS operates numerous pharmacies in the County.

[210] *AmerisourceBergen*, *supra* n.205.

408. Cardinal is a distributor of opioids in Sussex County and supplies various pharmacies in Sussex County an increasing amount of prescription opioid pills.

409. Cardinal distribution centers are required to operate in accordance with laws and regulations governing the sale and distribution of Schedule II narcotics, such as opioids, within the State of New Jersey.

410. Federal law requires Cardinal Health to design and operate a system to disclose suspicious orders of controlled substances, as well as by failing to actually disclose such suspicious orders, as required of "registrants" by the federal CSA, 21 C.F.R. § 1301.74(b).

411. Cardinal Health failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the proper authorities of suspicious orders.

412. On December 23, 2016, Cardinal Health agreed to pay the United States $44 million to resolve allegations that it violated the Controlled Substances Act in Maryland, Florida and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA.

413. In the settlement agreement, Cardinal Health admitted, accepted and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

- "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)";
- "maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA's regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5)"; and
- "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305."

414. The settlement agreement was announced by the U.S. Attorney for the District of Maryland, Rod J. Rosenstein ("Rosenstein"), and the DEA Special Agent in Charge – Washington Field Division, Karl C. Colder ("Colder").[211]

415. In the press release announcing the settlement agreement, Rosenstein stated:

> "Pharmaceutical suppliers violate the law when they fill unusually large or frequent orders for controlled substances without notifying the DEA . . . . Abuse of pharmaceutical drugs is one of the top federal law enforcement priorities. Cases such as this one, as well as our $8 million settlement with CVS in February 2016, reflect the federal commitment to prevent the diversion of pharmaceutical drugs for illegal purposes."[212]

416. In the press release, Colder clarified that the settlement specifically concerned oxycodone:

> "DEA is responsible for ensuring that all controlled substance transactions take place within DEA's regulatory closed system. All legitimate handlers of controlled substances must maintain strict accounting for all distributions and Cardinal failed to adhere to this policy . . . . Oxycodone is a very addictive drug and failure to report suspicious orders of oxycodone is a serious matter. The civil penalty levied against Cardinal should send a strong message that all handlers of controlled substances must perform due diligence to ensure the public safety . . . ."[213]

417. It is foreseeable to Cardinal Health that failing to design and operate a system to disclose suspicious orders of controlled substances and/or failing to notify the DCU of suspicious orders would cause harm to the County.

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[211] Press Release, U.S. Attorney's Office for the District of Maryland, Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act (Dec. 23, 2016), https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.

[212] *Id.*

[213] *Id.*

G. The Pharmacy Defendants Failed to Track and Report Suspicious Sales as Required by New Jersey Law.

418. New Jersey law imposes duties and requirements on the conduct of the Pharmacy Defendants. These requirements establish a standard of care for pharmacy conduct.

419. New Jersey law requires pharmacists to review each controlled substance prescription and, prior to dispensing medication, make a professional determination that the prescription is effective and valid. *See* N.J.A.C. 13:45H-7.4, *see also* N.J.A.C. 13:45H-7.8.

420. What is more, N.J.A.C. 13:45H-7.4 states, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a *corresponding responsibility* rests with the pharmacist who fills the prescription."

421. Therefore, pharmacists are required to ensure that prescriptions for controlled substances are valid, and that they are issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.

422. Under New Jersey law, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances" N.J.A.C. 13:45H-2.1, and maintain and file complete and accurate inventory records with the appropriate state and federal regulators. *See* N.J.A.C. 13:45H-5.9 – 5.13.

423. In addition, pharmacists "shall inform the Drug Control Unit of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." N.J.A.C. 13:45H-2.4.

424. On information and belief, the Pharmacy Defendants failed to provide effective controls and procedures to guard against diversion of prescription opioids, failed

to maintain complete and accurate inventory records, and failed to report suspicious orders.

425. On information and belief, the Pharmacy Defendants regularly filled opioid prescriptions that would have been deemed questionable or suspicious by a reasonably-prudent pharmacy.

426. On information and belief, the Pharmacy Defendants have not adequately trained or supervised their employees at the point of sale to investigate or report suspicious or invalid prescriptions, or protect against corruption or theft by employees or others.

427. On information and belief, the Pharmacy Defendants utilize monetary compensation programs for certain employees that are based, in part, on the number of prescriptions filled and dispensed. This type of compensation creates economic disincentives within the companies to change their practices. For example, there have been reports of chain store supervisory personnel directing pharmacists to fill prescriptions regardless of the red flags presented.

428. The Pharmacy Defendants have violated a voluntarily-undertaken duty to the public which they have assumed by their own words and actions. In news reports and other public documents, it has been reported that the Pharmacy Defendants, through their words or actions, have assured the public that issues affecting public health and safety are the highest priority for them.

429. For example, in 2015, CVS publicly stated that, "the abuse of controlled substance pain medication is a nationwide epidemic that is exacting a devastating toll upon individuals, families and communities. Pharmacists have a legal obligation under state and federal law to determine whether a controlled substance was issued for a legitimate purpose

and to decline to fill prescriptions they have reason to believe were issued for a non-legitimate purpose."

430. In failing to take adequate measures to prevent filling of invalid or suspicious prescriptions, the Pharmacy Defendants have breached their duties under the "reasonable care" standard, professional duties under the relevant standards of professional practice, and requirements established by the laws of the State of New Jersey.

431. It is foreseeable to the Pharmacy Defendants that filling invalid or suspicious prescriptions for opioids would cause harm, including overdoses and deaths, to the County's citizens who may use the wrongfully-dispensed opioids.

432. It is also foreseeable to the Pharmacy Defendants that the County would be forced to bear substantial expenses because of the Pharmacy Defendants' acts. At all relevant times, the Pharmacy Defendants acted, knowing full well that the County, in its role of providing protection and care for its citizens, would provide or pay for additional medical services, emergency services, law enforcement, and other necessary services and that the County would be harmed by the loss of substantial economic productivity that contributes to the health and well-being of the County.

433. At all relevant times, the Pharmacy Defendants have engaged in improper dispensing practices, and continue to do so, despite knowing full well they could take measures to substantially eliminate their complicity in opioid diversion.

434. The Pharmacy Defendants were on notice of their ongoing negligence or intentional misconduct towards the County in part because of their history of being penalized for violating their duties and legal requirements in other jurisdictions.

V. TOLLING OF THE STATUE OF LIMITATIONS

A. Continuing Wrong Doctrine

435. Plaintiff contends it continues to suffer harm from the continual unlawful actions by the Defendants.

436. Because Defendants owed a continuing duty to Plaintiff not to commit the wrongful acts alleged in this Complaint, and committed a continual, cumulative pattern of tortious conduct, the continued tortious and unlawful conduct by the Defendants are continuing violations state law causing a distinct injury instead of continual ill effects from an original violation.

437. The effects of Defendants' violative acts are cumulative. The damages have not occurred all at once but have continued to occur after each violation and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated.

B. Discovery Rule Tolling

438. The County did not discover, and could not have discovered through the exercise of reasonable diligence and intelligence Defendants' role in the deceptive marketing of chronic opioid therapy or the resulting harm caused by Defendants' false and deceptive statements about the risks and benefits of long-term opioid use within the time period of any applicable statutes of limitation.

439. Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and deceptive conduct. Among other things, Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties and hiding behind the assumed credibility of these

individuals and organizations. Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. Finally, Defendants manipulated the scientific literature and distorted the meaning and import of studies. The lack of support for Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by Plaintiffs.

440. Plaintiffs did not know of the existence or scope of the Defendants' deception and could not have acquired such knowledge earlier through the exercise of reasonable diligence. For these reasons, all applicable statutes of limitation have been tolled by operation of the discovery rule.

C. Fraudulent Concealment Tolling

441. All applicable statutes of limitation have also been tolled by Defendants' knowing and active fraudulent concealment and denial of the facts alleged herein throughout the time period relevant to this action.

D. Estoppel

442. Defendants are equitably estopped from relying upon a statute of limitations defense, to the extent any such defense even applies to Plaintiff's claims, because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State, the Plaintiff, and Plaintiff's Community, that they were undertaking efforts to comply with their obligations under the state controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the County.

443. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action.

VI. CLAIMS

COUNT I

VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT ("RICO"), 18 U.S.C. § 1961, ET SEQ.

(Against the Manufacturer Defendants)

444. The County incorporates by reference each preceding paragraph as though fully set forth herein.

445. Plaintiff brings this Count on behalf of itself against the Manufacturer Defendants.

446. At all relevant times, the Marketing Defendants were "persons" within the meaning of 18 U.S.C. §1961(3), because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

447. The RICO statute makes it unlawful for any person employed by or associated with any enterprise engaged in or activities of which affect trade or commerce to conduct or participate, directly or indirectly, in the conduct of the enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt. 18 U.S.C. §1962(c)

448. As alleged above, at all relevant times, the Manufacturer Defendants, together with their agents, expanded the market for prescription opioids through a fraudulent and deceptive marketing campaign that over-emphasized the under-treatment of pain and deceptively marketed opioids by: (i) downplaying the risk of addiction; (ii) exaggerating their safety and effectiveness for the treatment of chronic long-term pain; (iii) representing them as abuse resistant or deterrent; or (iv) promoting them as safe and effective for other types of pain for which the drugs were not approved. In particular, the Manufacturer Defendants, along with other entities and individuals,

were employed by or associated with, and conducted or participated in the affairs of, the RICO enterprise (the "Opioid Marketing Fraud Enterprise"), whose purpose was to deceive opioid prescribers and the public into believing that opioids were safe and effective for the treatment of long-term chronic pain, and presented minimal risk of addiction. In doing so, they sought to maximize revenues from the design, manufacture, distribution and sale of opioids which, in fact, were highly addictive and often ineffective and dangerous when used for long term, chronic and other types of pain. As a direct and proximate result of their fraudulent scheme and common course of conduct, defendants were able to extract revenues of billions of dollars. As explained in detail below, the Manufacturer Defendants' years-long misconduct violated 18 U.S.C. § 1962(c).

THE OPIOID MARKETING FRAUD ENTERPRISE

449. At all relevant times, the Manufacturer Defendants, along with other individuals and entities, including unknown third parties involved in the marketing and sale of opioids, operated an "enterprise" within the meaning of 18 U.S.C. § 1961(4); *Turkette*, 452 U.S. at 580; *Boyle v. U.S.*, 556 U.S. 938, 944 (2009) because they are a group of individuals associated in fact, even though they are not a collective legal entity. The Opioid Marketing Fraud Enterprise: (a) had an existence separate and distinct from each of its component entities; (b) was separate and distinct from the pattern of racketeering in which the Manufacturer Defendants engaged; and (c) was an ongoing organization consisting of legal entities, including, but not limited to, the Manufacturer Defendants, employees and agents of the FSMB, APF, AAPM, APS and APA, as well as other entities and individuals, including physicians.

450. Within the Opioid Marketing Fraud Enterprise, there was a common communication network by which members exchanged information on a regular basis through the use of wires and mail. The Opioid Marketing Fraud Enterprise used this common communication

network for the purpose of deceptively marketing and selling opioids to the general public. When their products were contested by other parties, the enterprise members took action to hide the scheme to continue its existence.

451. The participants in the Opioid Marketing Fraud Enterprise were systematically linked to each other through corporate ties, contractual relationships, financial ties and continuing coordination of activities. Through the enterprise, the Manufacturer Defendants functioned as a continuing unit with the purpose of furthering the illegal scheme and their common purposes of increasing their revenues and market share, and minimizing losses. Each member of the Opioid Marketing Fraud enterprise shared in the bounty generated by the enterprise by sharing the benefit derived from increased sales of opioids and other revenue generated by the scheme to defraud prescribers and consumers in the County.

452. The Opioid Marketing Fraud Enterprise engaged in, indeed, continues to engage in the deceptive marketing of opioids by overstating the benefits and greatly understating the serious risks of using opioids for chronic long-term pain.

453. The enterprise has engaged in such activity for the purpose of maximizing the sale and profits of opioids.

454. To fulfill this purpose, the enterprise has advocated for and caused the over-prescription of opioids by marketing, promoting, advertising and selling opioids in the County. Their receipt of monies from such activities has affected trade and commerce. The enterprise's past and ongoing practices thus constitute a pattern of racketeering activity under 18 U.S.C. § 1961(5).

455. The Opioid Marketing Fraud Enterprise functioned by marketing and selling opioids to states, counties, cities, other municipalities, doctors, healthcare organizations and the

consuming public. Many of these opioid products are legitimate, including opioids used short-term for acute surgical and end-stage cancer pain. However, the Manufacturer Defendants as co-conspirators, through their illegal enterprise, engaged in a pattern of racketeering activity, which involves a fraudulent scheme to increase revenue for the Manufacturer Defendants and the other entities and individuals associated-in-fact with the enterprise's activities through the deceptive marketing and sale of opioids.

456. The Manufacturer Defendants participated in the operation and management of the Opioid Marketing Fraud Enterprise by directing its affairs, as described herein. While the Manufacturer Defendants participated in, and are members of the enterprise, they have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements and financial statements.

457. As detailed above, each of the Manufacturer Defendants relentlessly promoted opioids as being safe and effective for the treatment of long-term chronic pain and, often in contravention of the drug's own label, as having little to no risk of addiction. The Manufacturer Defendants' success in maximizing sales was due to the tight collaboration among the Manufacturer Defendants through and in collaboration with the pain foundations – a formidable partnership that marketed to hundreds of thousands of prescribers across the country, including prescribers in the County. The relationship was strengthened, in part, by individuals including physicians that held different leadership roles at different times across the various entities participating in the enterprise over the years.

458. On numerous occasions, the Manufacturer Defendants funded the pain foundations' marketing efforts. The Manufacturer Defendants specifically chose to partner with the pain

foundations and individual physicians to publish and otherwise disseminate misleading pro-opioid material, knowing the public and prescribers would be more receptive to statements made by what they perceived to be scholarly, neutral, third party sources.

459. The members of the Opioid Marketing Fraud Enterprise worked together to further the enterprise, by and among the following manner and means:

(a) jointly planning and executing a deceptive marketing campaign that minimized the risks and exaggerated the benefits of opioid treatment of chronic, long-term pain;

(b) concealing the addictive qualities of the opioids from prescribers and the public;

(c) misleading the public about the addictive quality and safety and efficacy of opioids;

(d) otherwise misrepresenting or concealing the highly dangerous nature of opioids from prescribers and the public;

(e) illegally marketing, selling and/or distributing opioids; and

(f) profiting from the sale of such products for uses for which they are unapproved, ineffective, or substantially increased known risks for abuse and addiction.

460. To achieve their common goals, the Manufacturer Defendants suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the addictive and often ineffective nature of opioids, including supporting and executing "education" efforts intended to circumvent and downplay warnings with the goal of increasing opioid acceptance, use, and sales.

461. The foregoing allegations support that the Manufacturer Defendants were part of an association of entities that shared a common purpose, had relationships across the various

members of the enterprise and collaborated to further the goals of the enterprise for a continuous period of time. The Manufacturer Defendants knowingly and intentionally engaged in deceptive marketing practices, and incentivized pain foundations, marketing firms and physicians to do so as well.

PATTERN OF RACKETEERING ACTIVITIES

462. To carry out and attempt to carry out the scheme to defraud, the Individual and Manufacturer Defendants, each of whom is a person associated in fact with the enterprise, did knowingly conduct and participate, directly and indirectly, in the conduct of the affairs of the enterprise through a pattern of racketeering activity in violation of 18 U.S.C. §§1341 (mail fraud) and 1343 (wire fraud), and included a conspiracy.

463. Specifically, the Manufacturer Defendants have committed, conspired to commit and/or aided and abetted in the commission of, or caused the commission of, at least two predicate acts of racketeering activity (specifically, violations of 18 U.S.C. §§1341 and 1343) within ten years of each other. The multiple acts of racketeering activity which the Manufacturer Defendants committed or aided and abetted in the commission of, or caused to commit, were related to each other, and also posed a threat of continued racketeering activity. They therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the Manufacturer Defendants' regular use of the facilities, services, distribution channels and employees of the enterprise. The Manufacturer Defendants participated in the scheme to defraud by using, or causing the use of, mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce and by engaging in a conspiracy.

464. In devising and executing the illegal scheme, the Manufacturer Defendants devised and knowingly carried out a material scheme and/or artifice to defraud regulators, prescribers and

the public to obtain money from the County by means of materially false or fraudulent pretenses, representations, promises or omissions of material facts. For the purpose of executing the illegal scheme, the Manufacturer Defendants committed, or caused the commission of, these racketeering acts intentionally and knowingly with the specific intent to advance the illegal scheme.

465. The predicate acts of racketeering committed by, or cause to be committed by, the Manufacturer Defendants include, but are not limited to:

(a) Mail Fraud: The Manufacturer Defendants violated 18 U.S.C. §1341 by sending and receiving, and by causing to be sent and/or received, materials via U.S. Mail or commercial interstate carriers for the purpose of executing the unlawful scheme to deceptively market, and sell the opioids by means of false pretenses, misrepresentations, promises and omissions; and

(b) Wire Fraud: The Manufacturer Defendants violated 18 U.S.C. §1343 by transmitting and/or receiving, and by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to defraud and obtain money on false pretenses, misrepresentations, promises and omissions.

466. The Manufacturer Defendants' use of the mails and wires (or causing the issue thereof) include, but are not limited to, the transmission, delivery and shipment of deceptive marketing materials by the Manufacturer Defendants and other members of the Opioid Marketing Fraud Enterprise. These materials would not have been delivered but for the Manufacturer Defendants' illegal scheme, including, but not limited to:

(a) the FSMB's publication of opioid prescribing guidelines entitled "Responsible Opioid Prescribing," by Fishman;

(b) the FSMB's publication of "Revised and Expanded 2nd Edition [of] Responsible Opioid Prescribing[:] A Guide for Florida Clinicians";

(c) the APF's publication of Exit Wounds;

(d) the AAPM's "consensus statement" and educational programs featuring Fine;

(e) the APA's publication and dissemination of "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse";

(f) false or misleading communications to the public and to regulators;

(g) sales and marketing materials, including slide decks, presentation materials, purported guidelines, advertising, web sites, product packaging, brochures, labeling and other writings which misrepresented, falsely promoted and concealed the true nature of opioids;

(h) documents intended to facilitate the manufacture and sale of opioids, including bills of lading, invoices, shipping records, reports and correspondence;

(i) documents to process and receive payment for opioids, including invoices and receipts;

(j) payments to the foundations and physicians that deceptively marketed the Manufacturer Defendants' opioids;

(k) deposits of proceeds; and

(l) other documents and things, including electronic communications.

467. The Manufacturer Defendants also used, or caused the use of, the Internet and other electronic facilities to carry out the scheme and conceal the ongoing fraudulent activities. Specifically, the Manufacturer Defendants made misrepresentations about opioids on their websites, YouTube and through online ads, all of which intended to mislead prescribers and the

public about the safety, efficacy and about the seriousness of the addiction risk associated with opioids.

468. The Manufacturer Defendants also communicated, or caused communications, by U.S. Mail, by interstate facsimile and by interstate electronic mail with various other affiliates, regional offices, divisions, distributors and other third party entities in furtherance of the scheme. The mail and wire transmissions described herein were made in furtherance of the Manufacturer Defendants' scheme and common course of conduct to deceive prescribers and consumers and lure consumers into purchasing opioids by greatly overstating the effectiveness of opioids and by claiming that the risk of abuse and addiction was actually insignificant. The Manufacturer Defendants utilized mail and wire transmissions, or caused the use thereof, to create an extensive campaign that advertised the exact opposite message: that opioids were effective and rarely if ever addictive.

469. Many of the precise dates of the fraudulent uses of the U.S. Mail and interstate wire facilities are concealed from the County, and details as to the predicate acts is exclusively within the possession, custody or control of the Manufacturer Defendants. As such, it cannot be alleged without access to the Manufacturer Defendants' books and records. However, the County has described the types of predicate acts of mail and/or wire fraud that occurred. The secretive nature of the enterprise's activities made its marketing tactics even more deceptive and harmful.

470. The foregoing allegations support that the Manufacturer Defendants engaged in a pattern of racketeering activity by repeatedly engaging in wire and mail fraud, and a conspiracy, to deceptively market their products through the use of both print and electronic outlets.

471. The Manufacturer Defendants' pattern of racketeering activity has adversely impacted this State's trade or commerce, as well as the general health and welfare of the State and

its inhabitants. Their conduct annually drains and diverts millions from the public coffers and, as a consequence, harms the general health and welfare of the States' inhabitants, among other things.

CONSPIRACY ALLEGATIONS

472. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

473. The Manufacturer Defendants have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. In violation of under 18 U.S.C. § 1962(d) the Manufacturer Defendants conspired to violate under 18 U.S.C.§1962(c), as described herein.

474. The Manufacturer Defendants conspired to incentivize and encourage various other persons, firms and corporations, including third party entities and individuals not named as defendants in this Complaint, to carry out offenses and other acts in furtherance of the conspiracy. The Manufacturer Defendants conspired to increase or maintain revenues, increase market share and/or minimize losses for the Manufacturer Defendants and their other collaborators throughout the illegal scheme and common course of conduct. In order to achieve this goal, the Manufacturer Defendants engaged in the aforementioned predicate acts on numerous occasions. The Manufacturer Defendants, with knowledge and intent, agreed to the overall objectives of the conspiracy and participated in the common course of conduct to commit acts of fraud and indecency in defectively marketing and/or selling opioids through the use of mail and wire fraud.

475. For the conspiracy to succeed, each of the Manufacturer Defendants had to agree to deceptively market and/or sell opioids. Indeed, the unanimity of the Manufacturer Defendants' marketing tactics gave their misleading statements credence to prescribers and consumers.

476. The Manufacturer Defendants knew that by partnering with the pain foundations and individual physicians who carried a more neutral public image, they would be able to attribute more scientific credibility to their products, thereby increasing their sales and profits.

477. The foregoing illustrates the Manufacturer Defendants' liability under 18 U.S.C. § 1962(c) to engage in their pattern of racketeering conspired to achieve their common goal of maximizing opioid sales.

RESULTING DAMAGES

478. As described herein, the Manufacturer Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from consumers, based on their misrepresentations and omissions. The predicate acts also had the same or similar results, participants, victims and methods of commission. The predicate acts were related and not isolated events. The predicate acts all had the purpose of generating significant revenue and profits for the Manufacturer Defendants, at the expense of the County and its residents. The predicate acts were committed or caused to be committed by the Manufacturer Defendants through their participation in the enterprise and in furtherance of their fraudulent scheme, and were interrelated in that they involved obtaining the County's and its residents' funds.

479. The County and its residents, along with scores of other cities and municipalities, relied upon representations and omissions that were made or caused by the Manufacturer Defendants. The County's residents purchased opioids whose use has now caused an epidemic of addiction to opioids (both prescription and heroin).

480. The County's injuries, and those of its residents, were proximately caused by the Manufacturer Defendants' racketeering activity. The County was directly injured by the

Manufacturer Defendants' conduct because they caused the over-prescription of opioids and thus the over-purchase and over-consumption of opioids (both prescription and in the form of heroin).

481. By reason of, and as a result of the conduct of the Manufacturer Defendants, and in particular, their pattern of racketeering activity, the County and its residents have been injured financially in multiple ways, including, but not limited to, suffering increased expenditures for emergency services, law enforcement, public works, lost economic opportunity, lost productivity, increased expenditures for overtime, additional County employees, and mental health treatment for those employees, and lost tax revenue.

482. The Manufacturer Defendants' violations of 18 U.S.C. § 1962(c) have directly and proximately caused injuries and damages to the County and its residents, and the County is entitled to bring this action for three times its actual damages, as well as injunctive/equitable relief, costs and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c).

COUNT II

VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT ("RICO"), 18 U.S.C. § 1961, ET SEQ.

(Against Manufacturer and Distributor Defendants)

483. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

484. Plaintiff brings this Count on behalf of itself against the Manufacturer Defendants and the Distributor Defendants (collectively, for purposes of this Count, the "RICO Diversion Defendants").

485. The RICO Diversion Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise.

486. At all relevant times, the RICO Diversion Defendants were "persons" within the meaning of 18 U.S.C. §1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

487. In addition, IMS Health was a "person" within the meaning of 18 U.S.C. §1961(3) because it is an entity capable of holding, and does hold, "a legal or beneficial interest in property."

488. The RICO Diversion Defendants' illegal scheme was hatched by an association-in-fact enterprise between the Individual Defendants, the Manufacturer Defendants, and the Distributor Defendants. Each of the RICO Diversion Defendants were associated with, and conducted or participated in, the affairs of the RICO enterprise (defined below and referred to collectively as the "Opioid Diversion Enterprise"), whose purpose was to engage in the unlawful sales of opioids, deceiving the public and state regulators into believing that the RICO Diversion Defendants were faithfully fulfilling their statutory obligations.

489. The RICO Diversion Defendants' scheme allowed them to make billions in unlawful sales of opioids with the purpose of ensuring unlawfully increasing revenues, profits, and market share.

490. As a direct result of the RICO Diversion Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, entities like the Plaintiff experienced tens of millions of dollars of injuries caused by the reasonably foreseeable consequences of the opioid epidemic.

491. As explained in detail below, the RICO Diversion Defendants' misconduct violated 18 U.S.C. § 1962(c) and Plaintiff is entitled to treble damages for its injuries under 18 U.S.C. § 1964(c).

492. Alternatively, the RICO Diversion Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the RICO Diversion Defendants conducted their pattern of racketeering activity in this jurisdiction. Specifically, the Healthcare Distribution Alliance (the "HDA")[214] is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

493. On information and belief, each of the RICO Diversion Defendants is a member, participant, and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

494. Each of the RICO Diversion Defendants is a legal entity separate and distinct from the HDA. And, the HDA serves the interests of distributors and manufacturers beyond the RICO Diversion Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the RICO Diversion Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO enterprise.

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[214] History, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/hda-history (last accessed on February 20, 2018).

495. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the RICO Diversion Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the "Opioid Diversion Enterprise."

THE OPIOID DIVERSION ENTERPRISE

496. At all relevant times, the RICO Diversion Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by disregarding their statutory duty to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market. The RICO Diversion Defendants conducted their pattern of racketeering activity in this jurisdiction through this enterprise.

497. The Opioid Diversion Enterprise has been conducting business uninterrupted since its genesis.

498. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each RICO Distribution Defendant; (b) was separate and distinct from the pattern of racketeering in which the RICO Diversion Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Diversion Defendants; (d) characterized by interpersonal relationships among the RICO Diversion Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit.

499. Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the growth of profits generated

as a result of the Opioid Diversion Enterprise's disregard for its duty to prevent diversion of their drugs into the illicit market

500. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the RICO Diversion Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating state law requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of the RICO Distribution Defendants' scheme was to increase profits from opioid sales. The RICO Diversion Defendants refused to identify, investigate and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market.

501. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the RICO Diversion Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

502. Each of the RICO Diversion Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The RICO Diversion Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the RICO Diversion Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different

offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

503. The RICO Diversion Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the Pain Care Forum, the HDA, and through their contractual relationships.

504. The Pain Care Forum ("PCF") is a coalition of drugmakers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF shaped public policy regarding the use of prescription opioids for more than a decade.

505. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drugmakers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[215] Specifically, PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[216]

506. Not surprisingly, each of the RICO Diversion Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.[217] In 2012, membership and participating organizations included the HDA (of which all RICO Diversion Defendants are members), Endo, Purdue, Johnson & Johnson (the parent company for

[215] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo- chamber-shaped-policy-amid-drug-epidemic (emphasis added).

[216] *Id.*

[217] PAIN CARE FORUM, 2012 Meetings Schedule, Pain Care Forum (December 2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf.

Janssen Pharmaceuticals), and Teva (the parent company of Cephalon).[218] The Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise.

507. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.[219] The Distributor Defendants participated directly in the PCF as well.

508. The 2012 Meeting Schedule for the PCF is particularly revealing on the subject of the Defendants' interpersonal relationships. The meeting schedule indicates that meetings were held in the D.C. office of Powers, Pyles, Sutter & Verville, on a monthly basis, unless otherwise noted. Local members were "encouraged to attend in person" at the monthly meetings. And, the meeting schedule indicates that the quarterly and year-end meetings included a "Guest Speaker."[220]

509. The 2012 Pain Care Forum Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drugmakers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.[221]

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[218] *Id*. Plaintiff is informed and believes that Mallinckrodt became an active member of the PCF sometime after 2012.

[219] *Id*. The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. Executive Committee, Healthcare Distribution Alliance (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/executive-committee.

[220] Pain Care Forum, 2012 Meetings Schedule.

[221] *Id.*

510. Second, the HDA led to the formation of interpersonal relationships and an organization between the RICO Diversion Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants named in the Complaint, including, Endo, Purdue, Mallinckrodt and Cephalon were members of the HDA. And, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[222] Clearly, the HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturers and Defendants.

511. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the RICO Diversion Defendants.[223] The manufacturer

[222] Manufacturer Membership Benefits, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en, (last accessed on February 20, 2018).

[223] Manufacturer Membership Application, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-application.ashx?la=en, (last accessed on February 20, 2018).

membership application must be signed by a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.[224]

512. After becoming HDA members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, including:

(a) Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."

(b) Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participants in this committee include distributors and manufacturer members.

(c) Health, Beauty and Wellness Committee: "This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain." Participation in this committee includes distributors and manufacturer members.

(d) Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within

[224] *Id.*

the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.

(e) Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.

(f) Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.

(g) eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.

(h) ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.

(i) Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation includes Distributor and Manufacturer Members. [225]

[225] Councils and Committees, Healthcare Distribution Alliance, https://www.hda.org/about/councils-and-committees, (last accessed on February 20, 2018).

513. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise's organization.

514. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA, and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues." The conferences also gave the Manufacturer and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry." [226] The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. And, it is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.

515. Third, the RICO Diversion Defendants maintained their interpersonal relationships by working together and exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

516. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids. As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturers paid the Distributors rebates and/or

[226] 2017 Business and Leadership Conference, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2017-business-and-leadership-conference, (last accessed on February 20, 2018).

chargebacks on their prescription opioid sales. On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices. The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

517. The contractual relationships among the RICO Diversion Defendants also include vault security programs. The RICO Diversion Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. Plaintiff is informed and believes that manufacturers negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. Plaintiff is informed and believes that these agreements were used by the RICO Diversion Defendants as a tool to violate their reporting and diversion duties in order to reach the sales requirements.

518. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry.

519. Indeed, the Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The RICO Diversion Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the PCF are but two examples

of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the RICO Diversion Defendants was in communication and cooperation.

520. According to articles published by the Center for Public Integrity and The Associated Press, the PCF -- whose members include the Manufacturers and the Distributors' trade association has been lobbying on behalf of the Manufacturers and Distributors for "more than a decade." [227]

521. And, from 2006 to 2016 the Distributors and Manufacturers worked together through the Pain Care Forum to spend over $740 million lobbying in the nation's capital and in all 50 statehouses on issues including opioid-related measures. [228] Similarly, the HDA has continued its work on behalf of Distributors and Manufacturers, without interruption, since at least 2000. [229]

522. As described above, the RICO Diversion Defendants began working together as early as 2006 through the PCF and/or the HDA to promote the common purpose of their enterprise. Plaintiff is informed and believes that the RICO Diversion Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

523. The RICO Diversion Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report suspicious orders of opioids in order to

[227] Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic

[228] *Id.*

[229] History, Healthcare Distribution Alliance

prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales and, in doing so, to drive unlawful profits, as follows:

524. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

525. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

526. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DCU of any suspicious orders or diversion of their prescription opioids.

527. Defendants sought to influence local, state and federal governments through joint lobbying efforts as part of the PCF. The RICO Diversion Defendants were all members of their PCF either directly or indirectly through the HDA.

528. The RICO Diversion Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

529. The RICO Diversion Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. The Manufacturer Defendants used the chargeback program to acquire detailed, high-level data regarding sales of the opioids they manufactured.

530. The Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

531. The Distributor Defendants developed "know your customer" questionnaires and files.

532. On information and belief, the "know your customer" questionnaires informed the RICO Diversion Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

533. The RICO Diversion Defendants refused to identify, investigate and report suspicious orders to the DCU when they became aware of the same despite their actual knowledge of drug diversion rings.

534. Defendants' scheme had a decision-making structure that was driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the State's response to the manufacture and distribution of prescription opioids through a systematic refusal to maintain effective controls against diversion, and identify suspicious orders and report them to the DCU.

535. Indeed, the RICO Diversion Defendants actively took steps to increase suspicious orders in the following ways:

(a) The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the PCF;

(b) The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;

(c) The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;

(d) The Manufacturer Defendants used sales information showing how individual doctors across the nation were prescribing opioids.

(e) The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

(f) The Manufacturer Defendants used the Distributor Defendants' sales information and the data to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;

(g) The RICO Diversion Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market; and

(h) The RICO Diversion Defendants withheld information regarding suspicious orders and illicit diversion from the DCU.

536. The scheme devised and implemented by the RICO Diversion Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

PATTERN OF RACKETEERING ACTIVITY

537. The RICO Diversion Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity including mail fraud (18 U.S.C. § 1341), wire fraud (18 U.S.C. § 1343), and violations of the Controlled Substances Act, 21 U.S.C. § 801, et seq. ("CSA" or "Controlled Substances Act").

538. The RICO Diversion Defendants carried out, or attempted to carry out, a scheme to defraud state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(5), that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

539. The RICO Diversion Defendants committed, conspired to commit, and/or aided and abetted in the commission of, or caused the commission of, at least two predicate acts of racketeering activity (specifically, violations of 18 U.S.C. §§ 1341 and 1343) within ten years of each other. The multiple acts of racketeering activity that the RICO Diversion Defendants committed, or aided and abetted in the commission of, or caused the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Diversion Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioids Diversion Enterprise. The RICO Diversion Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

540. The RICO Diversion Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

541. In devising and executing the illegal scheme, the RICO Diversion Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the RICO Diversion Defendants committed, or caused to be committed, these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

542. The predicate acts of racketeering committed by, or caused to be committed by, the RICO Diversion Defendants (18 U.S.C. § 1961(1)) include, but are not limited to:

(a) Mail Fraud: The RICO Diversion Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

(b) Wire Fraud: The RICO Diversion Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

543. The RICO Diversion Defendants' use of, or causing the use of, the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third parties that were foreseeably caused to be sent as a result of the RICO Diversion Defendants' illegal scheme, including but not limited to:

(a) The prescription opioids themselves;

(b) Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;

(c) Defendants' registrations to sell, manufacturer, and/or distribute prescription opioids within the State of New Jersey;

(d) Documents intended to facilitate the manufacture, distribution, and sale of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

(e) Documents for processing and receiving payment for prescription opioids;

(f) Payments between the Distributors and the Manufacturers;

(g) Rebates and chargebacks from Manufacturers to the Distributors;

(h) Payments to Defendants' lobbyists through the PCF;

(i) Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

(j) Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and

(k) Other documents and things, including electronic communications.

544. On information and belief, the RICO Diversion Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

(a) Purdue manufactures multiple forms of prescription opioids, including but not limited to: OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq

ER. Purdue manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction. The Distributor Defendants shipped Purdue's prescription opioids throughout this jurisdiction.

(b) Cephalon manufactures multiple forms of prescription opioids, including but not limited to: Actiq and Fentora. Cephalon manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction. The Distributor Defendants shipped Cephalon's prescription opioids throughout this jurisdiction.

(c) Janssen manufactures prescription opioids known as Duragesic. Janssen manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction. The Distributor Defendants shipped Janssen's prescription opioids throughout this jurisdiction.

(d) Endo manufactures multiple forms of prescription opioids, including but not limited to: Opana/Opana ER, Percodan, Percocet, and Zydone. Endo manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction. The Distributor Defendants shipped Janssen's prescription opioids throughout this jurisdiction.

(e) Mallinckrodt manufactures multiple forms of prescription opioids, including but not limited to: Exalgo and Roxicodone. The Distributor Defendants shipped Mallinckrodt's prescription opioids throughout this jurisdiction.

(f) Insys manufactures Subsys (fentanyl). The Distributor Defendants shipped Insys' prescription opioids throughout this jurisdiction.

545. The RICO Diversion Defendants also used, or caused the use of, the internet and other electronic facilities to carry out their scheme and conceal their ongoing fraudulent activities. Specifically, the RICO Diversion Defendants made misrepresentations about their compliance

with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

546. At the same time, the RICO Diversion Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids and that they complied with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

547. Plaintiff is also informed and believes that the RICO Diversion Defendants utilized, or caused the utilization of, the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

548. The RICO Diversion Defendants also communicated by, or caused communication by, U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

549. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market.

550. Many of the precise details of the fraudulent uses of the U.S. mail and interstate wire facilities, and other predicate acts, have been deliberately hidden by, and is exclusively within the possession, custody or control of, the RICO Diversion Defendants. As such, it cannot be alleged without access to Defendants' books and records. But, Plaintiff has described the types of,

and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

551. The RICO Diversion Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the RICO Diversion Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Diversion Defendants.

552. The RICO Diversion Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§1341 and 1343 offenses.

553. The RICO Diversion Defendants hid from the general public, and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that the RICO Diversion Defendants were filling on a daily basis -- leading to the diversion of a tens of millions of doses of prescriptions opioids into the illicit market.

554. The RICO Diversion Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

555. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

556. The RICO Diversion Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

557. The predicate acts all had the purpose of generating significant revenue and profits for the RICO Diversion Defendants while Plaintiff was left with substantial injury to its business through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the RICO Diversion Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

558. The pattern of racketeering activity alleged herein and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

559. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

560. Many of the precise dates of the RICO Diversion Defendants' criminal actions at issue here have been hidden, are exclusively within the possession, custody or control, of the RICO Diversion Defendants, and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioids Addiction and Opioid Diversion Enterprise alleged herein depended upon secrecy.

561. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and the Plaintiff.

562. The RICO Diversion Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on communities in this jurisdiction or the Plaintiff.

563. In designing and implementing the scheme, at all times the RICO Diversion Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding the RICO Diversion Defendants' products and their manufacture and distribution of those products.

564. The RICO Diversion Defendants were also aware that Plaintiff and the citizens of this jurisdiction rely on them to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

565. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the RICO Diversion Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

566. It was foreseeable to the RICO Diversion Defendants that refusing to report and halt suspicious orders, as required by law, would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

567. The last racketeering incident occurred within ten years of the commission of a prior incident of racketeering. The RICO Diversion Defendants conducted and participated in the

conduct of the affairs of the RICO Diversion Enterprise through a pattern of racketeering activity as defined in by violating Controlled Substances Act.

568. Specifically, the CSA makes it unlawful for a registered manufacturer or distributor to furnish false or fraudulent material information in, or omit any material information from, any application, report, or other document required to be kept or filed under the act, or any record required to be kept by the act.

569. Additionally, under the CSA it is unlawful to refuse or fail to make, keep or furnish any record, notifications, order form, statement, invoice or information required under the act.

570. Each of the RICO Diversion Defendants qualifies as a registrant under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances, and inform the DCU of orders of unusual size when discovered by the registrant.

571. Pursuant to Federal law, the RICO Diversion Defendants were required to make reports and furnish records to the proper authorities of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

572. The RICO Diversion Defendants knowingly and intentionally furnished false or fraudulent information in their reports about suspicious orders, and omitted material information from reports, records, and other documents required to be filed with the DEA. Specifically, on information and belief, the RICO Diversion Defendants were aware of suspicious orders of prescription opioids and their diversion into the illicit market, and failed to report this information to the DEA in their mandatory reports.

573. Distributors knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. On information and belief, the Manufacturer Defendants were aware of the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

574. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

575. Many of the precise dates of Defendants' criminal actions at issue herein were hidden, are exclusively within the possession, custody or control, of the Defendants, and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

576. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and the Plaintiff. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiff. The Defendants were aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

577. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

578. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by law, would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

579. The last racketeering incident occurred within ten years of the commission of a prior incident of racketeering.

580. The RICO Diversion Defendants' pattern of racketeering activity has adversely impacted this State's trade or commerce, as well as the general health and welfare of the State and its inhabitants. Their conduct annually drains and diverts millions from the public coffers, and as a consequence harms the general health and welfare of the States' inhabitants, among other things.

CONSPIRACY ALLEGATIONS

581. Plaintiff realleges and incorporates by reference all paragraphs as though fully set forth herein.

582. The Manufacturer Defendants and Distributor Defendants have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. § 1962(d) the Manufacturer Defendants conspired to violate 18 U.S.C. § 1962(c). as described herein.

583. The Manufacturer Defendants and Distributor Defendants conspired to incentivize and encourage various other persons, firms and corporations, including third party entities and individuals not named as defendants in this Complaint, to carry out offenses and other acts in furtherance of the conspiracy. The Manufacturer Defendants and Distributor Defendants

conspired to increase or maintain revenues, increase market share and/or minimize losses for the Manufacturer Defendants and Distributor Defendants and their other collaborators throughout the illegal scheme and common course of conduct. In order to achieve this goal, the Manufacturer Defendants and Distributor Defendants engaged in the aforementioned predicate acts on numerous occasions. The Manufacturer Defendants and Distributor Defendants, with knowledge and intent, agreed to the overall objectives of the conspiracy and participated in the common course of conduct to commit acts of fraud and indecency in defectively marketing and/or selling opioids through the use of mail and wire fraud.

584. Each of the Manufacturer Defendants and Distributor Defendants agreed to conduct or participate in the conduct of the affairs of the enterprise, and agreed to the commission of at least two predicate acts. They also engaged in a RICO conspiracy based on their agreement to the scheme to deceptively market and/or sell and/or distribute opioids, or based on their adoption of the goal of furthering or facilitating the scheme.

585. The Manufacturer Defendants and Distributor Defendants knew and intended that state regulators, prescribers and consumers in the County, would rely on the collective material misrepresentations and omissions made by them and the other enterprise members about opioids. The Manufacturer Defendants and Distributor Defendants knew and intended that consumers, including those in the County, would incur costs as a result.

586. The foregoing illustrates the Manufacturing Defendants' and Distributor Defendants' liability under 18 U.S.C. § 1962(d) to engage in their pattern of racketeering conspired to achieve their common goal of maximizing opioid sales.

RESULTING DAMAGES

587. The RICO Diversion Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property because Plaintiff paid for costs associated with the opioid epidemic, as described above in language expressly incorporated herein by reference.

588. Plaintiff's injuries, and those of her citizens, were proximately caused by Defendants' racketeering activities. But for the RICO Diversion Defendants' conduct, Plaintiff would not have paid for the health services, social services and first responders' services and other expenditures required to deal with the impact of the epidemic on the County and her citizens.

589. Plaintiff's injuries were directly caused by the RICO Diversion Defendants' racketeering activities.

590. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

591. Plaintiff seeks all legal and equitable relief as allowed by law, including inter alia actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

COUNT III

PUBLIC NUISANCE

592. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if fully set forth herein.

593. A public nuisance is an unreasonable interference with a right common to the general public, such as a condition dangerous to health, offensive to community moral standards, or unlawfully obstructing the public in the free use of public property.

594. The County and its residents have a right to be free from conduct that endangers their health and safety. The health and safety of the residents of the County are matters of substantial public interest and of legitimate concern to the County. Yet Defendants, individually and collectively, have engaged in conduct which endangers or injures the health and safety of the residents of the County by their promotion, marketing, distribution, and overall efforts to increase the use and sales of opioids (including use and sales within the County) and by their failure to monitor, report and prevent such abuses and/or injurious distribution and prescriptions.

595. Defendants, each individually and collectively, have created a condition that is injurious to the health and safety of the County and its residents and interferes with the comfortable enjoyment of life and property of entire communities and/or neighborhoods. Through their production, promotion, and marketing of opioids for use by residents of the County and by their failure to monitor, report and prevent over-prescription, improper prescriptions, and diversion, the Defendants have created or assisted in creating the opioid epidemic within the County.

596. The epidemic, with its associated increase in deaths, injuries, crime and homelessness, has severely disrupted public peace and order and endangered public health and safety. Defendants' conduct is ongoing and continues to produce permanent and long-lasting damage.

597. The health and safety of the residents of the County, including those who use, have used, or will use opioids, as well as those affected by users of opioids, are matters of substantial public interest and of legitimate concern to the County's citizens and its residents.

Defendants' conduct has impacted and continues to impact a substantial number of people within the County and is likely to continue causing significant harm to patients with chronic pain who are being prescribed and take opioids, their families, and their communities.

598. But for Defendants' actions, there is no doubt that opioid use and ultimately its misuse and abuse would not be as widespread as it is today, and the massive epidemic of opioid abuse that currently exists would have been averted.

599. Logic, common sense, justice, policy, and precedent indicate Defendants' unfair and deceptive conduct has caused the damage and harm complained of herein. Defendants knew or reasonably should have known that their statements regarding the risks and benefits of opioids were false and misleading, and that their false and misleading statements and failures to monitor and curb and prevent abuse were causing harm. Thus, the public nuisance caused by Defendants to the County was reasonably foreseeable, including the financial and economic losses incurred by the County.

600. Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used, in deceiving healthcare professionals and patients about the risks and benefits of opioids for the treatment of chronic pain, and in the public health crisis that followed.

601. Defendants knew or should have known that their promotion of opioids was false and misleading and that their deceptive marketing scheme and other unlawful, unfair, and fraudulent actions would create or assist in the creation of a public nuisance.

602. Defendants' conduct in creating and maintaining the public nuisance were neither fully regulated nor required by any federal or New Jersey law, and in fact were contrary to public policy and guidance from the FDA and CDC.

603. The public nuisance alleged herein can be abated and further recurrence of such harm and inconvenience can be abated.

604. The County has been, and continues to be, directly and proximately injured by Defendants' actions in creating a public nuisance.

605. Plaintiff suffered special injuries distinguishable from those suffered by the general public.

606. Defendants' conduct was accompanied by wanton and willful disregard of persons who foreseeably might be harmed by their acts and omissions.

COUNT IV

NEGLIGENCE

607. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if fully set forth herein.

608. Each Defendant owed a duty of care to the County and her residents, including but not limited to taking reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.

609. In violation of this duty, Defendants failed to take reasonable steps to prevent, monitor, and/or report the misuse, abuse, and over-prescription of opioids in the County by misrepresenting the risks and benefits associated with opioids.

610. As alleged above, Defendants falsely claimed that the risk of opioid addiction was low, falsely instructed doctors and patients that prescribing more opioids was appropriate when patients presented symptoms of addiction, falsely claimed that risk-mitigation strategies could safely address concerns about addiction, falsely claimed that doctors and patients could increase opioid usage indefinitely without added risk, deceptively marketed that purported abuse-deterrent technology could curb misuse and addiction, falsely claimed that long-term opioid use could

actually restore function and improve a patient's quality of life, and failure to monitor and report opioid use and potential for misuse as required by law.

611. Each of these misrepresentations made by Defendants violated the duty of care to the County and her residents.

612. As a direct and proximate cause of Defendants' unreasonable and negligent conduct, the County and her residents have suffered and will continue to suffer harm, and are entitled to damages in an amount determined at trial.

COUNT V

CIVIL CONSPIRACY

613. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if fully set forth herein.

614. The Distributor Defendants continuously supplied prescription opioids to the Pharmacy Defendants despite having actual or constructive knowledge that said pharmacies were habitually breaching their common law duties and violating New Jersey law.

615. Without the Distributor Defendants' supply of prescription opioids, the Pharmacy Defendants would not be able to fill and dispense the increasing number of prescription opioids throughout the County.

616. The Pharmacy Defendants continuously paid the Distributor Defendants to supply large quantities of prescription opioids in order to satisfy the demand for the drugs.

617. Neither side would have succeeded in profiting so significantly from the opioid epidemic without the concerted conduct of the other party.

618. As a result of the concerted action between the Distributor Defendants and the

Pharmacy Defendants, the County and her citizens have suffered damage.

COUNT VI

CIVIL CONSPIRACY

619. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if fully set forth herein.

620. The Manufacturer Defendants continuously supplied prescription opioids to the Distributor Defendants despite having actual or constructive knowledge that the Distributor Defendants were habitually breaching their common law duties and violating state and federal law.

621. Without the Manufacture Defendants' supply of prescription opioids, the Distributor Defendants would not be able to fill and dispense the increasing number of prescription opioids throughout the County.

622. The Distributor Defendants continuously paid the Manufacturer Defendants to supply large quantities of prescription opioids in order to satisfy the demand for the drugs.

623. Neither side would have succeeded in profiting so significantly from the opioid epidemic without the concerted conduct of the other party.

624. As a result of the concerted action between the Manufacturer Defendants and the Distributor Defendants, the County and her citizens have suffered damage.

PRAYER FOR RELIEF

WHEREFORE, the County respectfully requests the Court order the following relief:

(a) An Order that the conduct alleged herein constitutes a public nuisance under New Jersey law;

(b) An Order that Defendants abate the public nuisance that they caused under New Jersey law;

(c) An Order that Defendants are negligent under New Jersey law;

(d) An Order that Defendants' conduct constitutes violations of the N Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.*;

(e) An Order that the conduct alleged herein constitutes a civil conspiracy under federal law;

(f) An Order that Plaintiff is entitled to treble damages pursuant to New RICO;

(g) An Order that Plaintiff is entitled to recover all measure of damages permissible under the statutes identified herein and under common law;

(h) An Order that judgment be entered against Defendants in favor of Plaintiff;

(i) An Order that Plaintiff is entitled to attorney's fees and costs pursuant to any applicable provision of law, including but not limited to under RICO; and

(j) An Order awarding any other and further relief deemed just and proper, including pre-judgment and post-judgment interest on the above amounts.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury.

/s/ *James E. Cecchi*

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